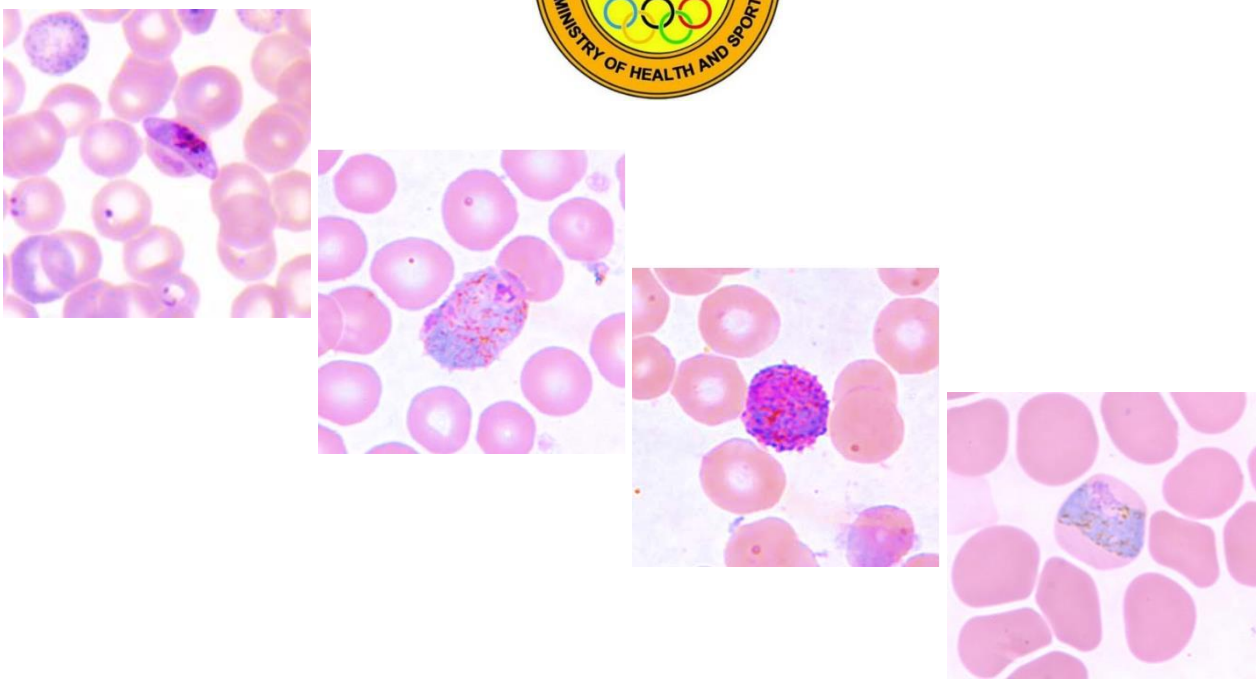

QUALITY ASSURANCE & QUALITY CONTROL MANUAL FOR MALARIA MICROSCOPY

MYANMAR

2017

Version 2

Foreword

Myanmar has reduced malaria incidence by 49% in 2015 in comparison to 2012. The control programme has now embarked into elimination aiming to eliminate *P. falciparum* by 2025 and malaria by 2030. Reducing malaria mortality and morbidity depends upon early diagnosis and prompt effective treatment of malaria. The fundamental to this goal of early diagnosis and effective treatment is the demonstration of the presence of malaria parasites in the blood film which is possible by malaria microscopy. If the accuracy of the clinical diagnosis is poor, it leads to over-diagnosis of malaria, poor management of non-malarial febrile illness and wastage of resources and also increasing resistance to antimalarials. The microscopy still remains the mainstay of parasite-based diagnosis in public health facilities and the quality of microscopy-based diagnosis is important to rely on the results. The over-diagnosis and under-diagnosis results in the poor patient outcomes and also the wastage of the resources.

National Malaria Control Programme is embarking into elimination and cases will remain in the public health facilities where the malaria microscopy is the main stay for diagnosis. The parasite can be demonstrated, different species and forms of parasite can be seen, parasite densities can be counted by this gold standard diagnostic test which is not possible by the rapid diagnostic test. However, to interpret the results as accurate, a well-functioning comprehensive Quality Assurance and Quality Control (QA/QC) programme is crucial for the malaria microscopy services. The aim of the QA programme is to ensure that the results obtained are accurate, reliable and reproducible. This is an outcome of pre-analytical, analytical and post-analytical procedures. Dedicated, motivated and trained staff with proper supervision and internal quality control procedures plays a crucial role along with the supply of quality reagents and equipment.

The manual focuses on the QA system, internal and external quality assessment, internal quality control, infrastructural requirement, supplies and equipment, training, supervision and monitoring and plan of action that is required for a well-functioning QA/QC programme. This document will be a guide for the NMCP and NHL for QA/QC for malaria microscopy.

I would fully endorse the QA/QC manual for malaria microscopy and ensure its full implementation.

Dr. Thar Tun Kyaw
Director General
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Version 1 was prepared by URC-CAP Malaria Project with the support of Dr. Khin Mon Mon, former National Malaria Control Programme Manager in 2015. In May 2016, "Malaria Surveillance and Quality Assurance System" project (URC-ADB project) was launched with the funding support from the Asian Development Bank (ADB). On 22nd July 2016 stakeholder meeting, H.E Union Minister for Health and Sports delivered speech on malaria laboratory quality assurance system that is essential for the malaria elimination by the year 2020. This project along with WHO provided technical support to NMCP to develop "Quality Assurance and Quality Control Manual" and "Standard Operation Procedures for Malaria Microscopy".

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National Malaria Control Program

Department of Public Health

Ministry of Health and Sports

Acronyms

ADB - Asian Development Bank
BHS - Basic Health Staff
COE - Centre of Excellence
DMR - Department of Medical Research
ECA - External Competency Assessment
EQA - External Quality Assurance
EQAS - External Quality Assessment Scheme
HA - Health Assistant
IQC - Internal Quality Control
Lab - Laboratory
LHV - Lady Health Visitor
MLT - Malaria Laboratory Technician
MO - Medical Officer
MP - Malaria Parasite
MRL - Malaria Reference Laboratory
NCA - National Competence Assessment
NGOs - Non government organizations
NHL - National Health Laboratory
NMCP - National Malaria Control Programme
NMRL - National Malaria Reference Laboratory
NRL - National Reference Laboratory
OTSS - Outreach Training and Supportive Supervision
PHS II - Public Health Supervisor II
QA - Quality Assurance
QC - Quality Control
QMS - Quality Management System
RDT - Rapid Diagnostic Test
RHC - Rural Health Centre
S&E - Supplies & Equipment
S/R - State/Region
SH - Station Hospital
SOP - Standard Operating Procedures
SWOT - Strength, Weakness, Opportunity and Threat
URC - University Research Co., LLC
VBDC - Vector Borne Disease Control
WHO - World Health Organization

Glossary

Quality is defined as a set of processes/ procedures which ensure that whatever function/assay is undertaken produces an outcome/result/product which is valid, accurate, reliable, and reproducible and has met all the quality standards laid down for the said function/assay.

Competency in microscopy, competence is the skill of a Lab Technician for performing an accurate examination and reporting of a malaria blood film.

External Quality Assessment Scheme (EQAS) involves specimens, of known but undisclosed content being introduced into the laboratory by designated "Apex/Reference" laboratory and examined by the staff of participating laboratory/ies using the same procedures as used for routine/normal specimens of the same type. This method checks the accuracy of the test results produced by the participating laboratories.

Internal Quality Control (IQC) describes all the activities taken by a laboratory to monitor each stage of a test procedure to ensure that tests are performed correctly that is accurately and precisely.

Performance of Laboratory Technician is the accuracy of a Lab Technician examining malaria slides in routine practice. For assessment of the performance of a Laboratory Technician setting standards of performance is a perquisite.

Standard Operating Procedures (SOPs) are the most important documents in a laboratory. These describe in details of the complete procedures for performing tests and ensures that consistent and reproducible results are generated.

Sensitivity is the probability that it will produce a true positive result when used in an infected population (as compared to a reference or "gold standard"). A highly sensitive test detects all the individuals who are infected but may also detect as few individuals who are not infected as positive.

Specificity is the probability that it will produce a true negative result when used on a non-infected population (as determined by a reference or "gold standard"). A highly specific test correctly identifies all the individuals who are not infected as negative, but may detect few infected cases (early infection, low parasitaemia cases) also as negative.

Quality Assurance (QA)

QA is the monitoring and maintenance of high accuracy, reliability and efficiency of laboratory services. Quality assurance addresses all factors that affect laboratory performance including test performance (quality control, internal and external) equipment and reagent quality, workload, workplace conditions, training and laboratory staff support.

Quality Control (QC)

QC measures the quality of a test or a reagent. For malaria microscopy, the most common form of quality control (QC) is the cross-checking of routine blood slides to monitor the

accuracy of examination. Quality control also encompasses external quality control and reagent quality control.

Cross-checking QC is a system whereby sample of routine blood slides are cross-checked for accuracy by a supervisor or the regional/national laboratory.

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.

National Malaria Control Programme (NMCP)

The countrywide programme 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 Malaria Reference Laboratory (NMRL)

This may be part of the central public health laboratory, the NMCP. 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 QA in collaboration with the NMCP.

Quality improvement

A process in which the components of microscopy and RDT diagnostic services are analyzed in order to identify and permanently correct any deficiencies. Data collection, data analysis and creative problem-solving are used.

S/N **Table of Contents** Page

Quality Assurance and Quality Control Manual for Malaria Microscopy (Myanmar)

1. INTRODUCTION

1.1 The Need for QA/QC of Malaria Microscopy

The detection of malaria parasites by light microscopy is still the Gold Standard of malaria diagnosis in health clinics and hospitals throughout the world. This requires a reliable microscopy service that:

- is cost-effective
- is accurate and timely
- has results with a direct impact on the treatment given to a patient.

The effectiveness of malaria microscopy depends on maintaining a high level of staff competency and performance at all levels.

1.2 The role of light microscopy in current malaria control practice and elimination strategies

- Laboratory diagnosis by microscopic examination of stained blood films continues to be the method of choice, or the common reference standard, for case management and epidemiological studies.
- Light microscopy is also essential for parasitic diagnosis during clinical and field trials of antimalarial drugs and vaccines and for the QA of other forms of malaria diagnosis, such as RDTs.

Microscope diagnosis has many advantages, including:

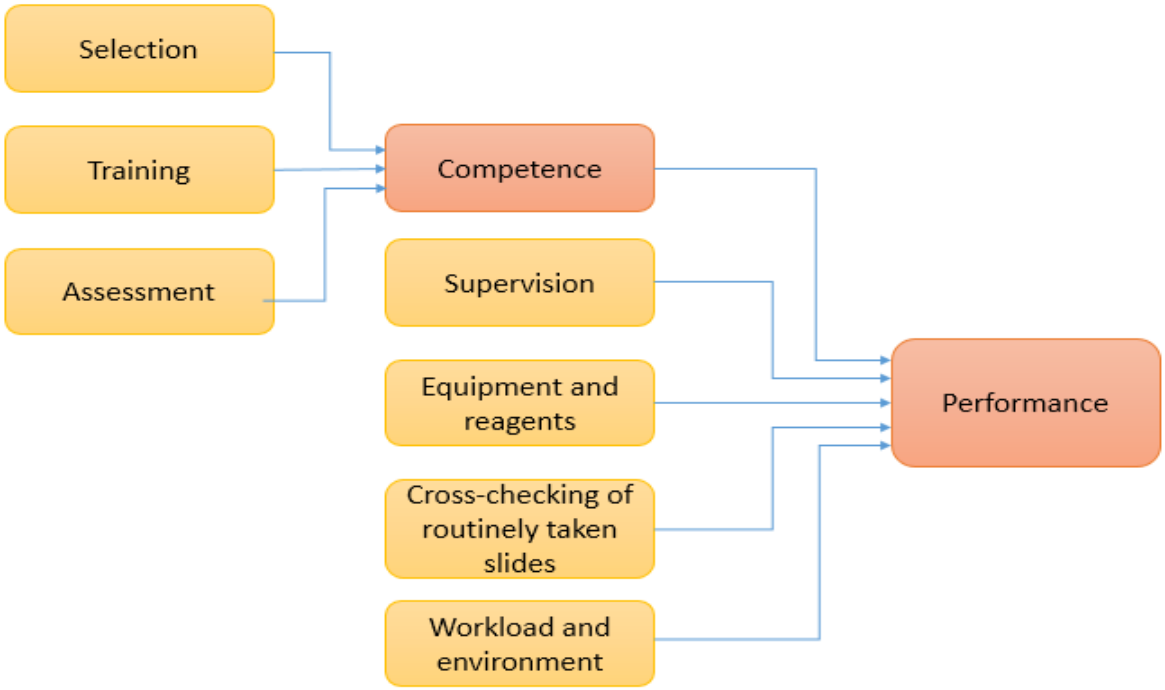
- low direct costs if there is already a high volume of samples and the infrastructure to maintain the service;
- highly sensitive for clinical malaria, if the quality of microscopy is good (including competent microscopists, good equipment and reagents and an appropriate workload), although not sensitive for detecting low-density parasitaemia;
- allows differentiation of malaria species and parasite stages;
- allows determination of parasite density;
- allows assessment of drug effects; and
- can be used to diagnose other diseases.

1.3 Improving competency and performance

A high level of competency and performance can only be achieved if microscopists at all levels are supported by a training, resources and assessment programme that is continuous, allows refresher training when required, is linked to career advancement for those who are high performers and is developed according to international standards[2].

In some settings, malaria microscopists do not even receive formal training and are expected to learn on the job from others, who often do not have the requisite skills and tools to train. Thus, microscopists with little competence often teach others, who in turn acquire less skill and feeding a cycle of low quality.

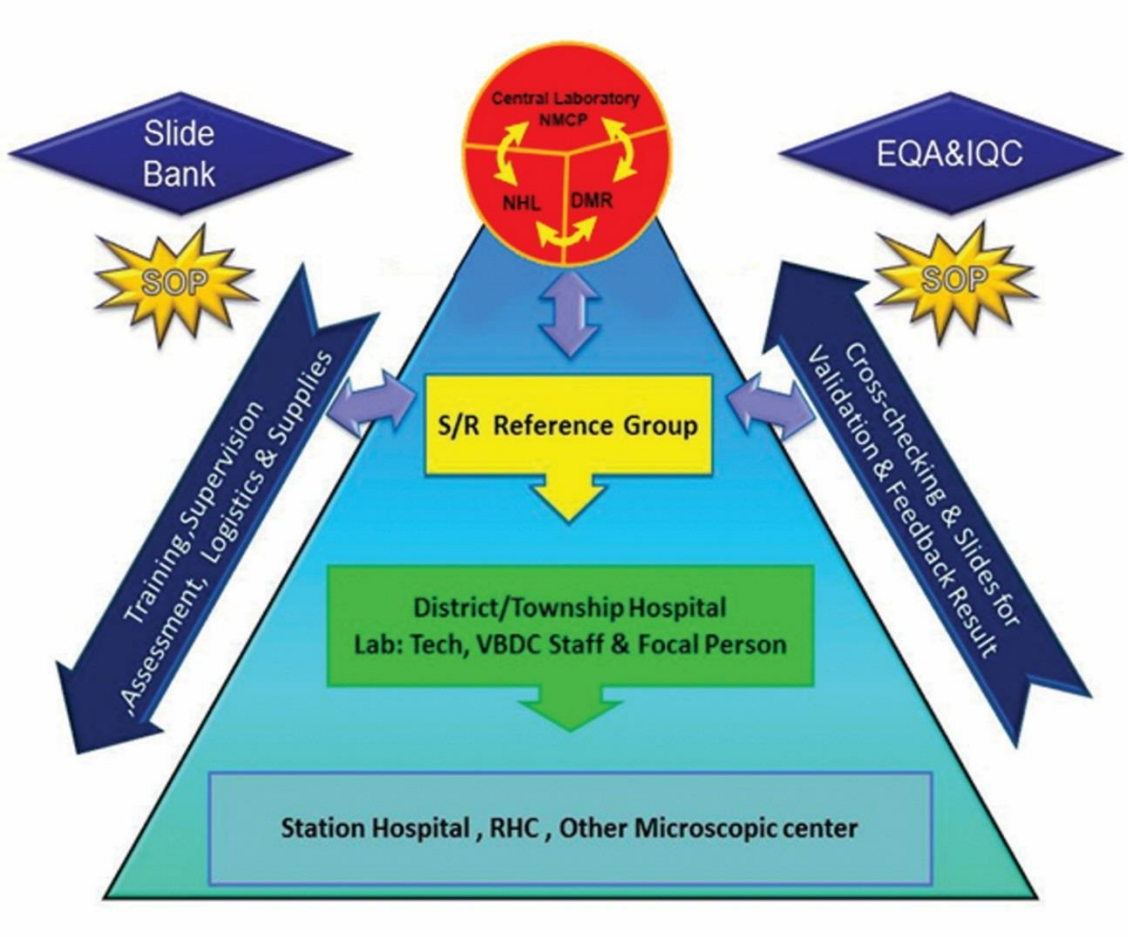
Figure 1. Ensuring and demonstrating good performance in malaria microscopy



2. STRUCTURE AND FUNCTION OF A QUALITY ASSURANCE SYSTEM

2.1 Basic structure and organization of Quality Assurance

Figure 2 – Organizational set up of Quality Assurance for Malaria Microscopy in Myanmar



Based on WHO recommendation, the malaria laboratory QA system should be part of malaria microscopy. In addition, the malaria microscopy and its QA system should be integrated with other microscopically diagnosed communicable diseases, under the Department of Public Health.

Three to 4 times of consultative meeting between NHL, NMCP, WHO and partners have been conducted to draft the National Quality Assurance Manual to reflect the Myanmar context in order to strengthen malaria diagnosis and its quality assurance. NMCP has more responsible for malaria quality microscopy and QA system. NMCP is also responsible for ensuring the logistical supply of reagents and equipment, reporting and evaluation of microscopy performance, which results in the optimal use of microscopes and quality results with minimum workloads.

2.1.1 Role of Laboratories at different levels

Establishment of national core group of certified, highly competent technicians and decision maker had been organized in 22nd July 2016 at the URC-ADB stakeholder meeting at Nay Pyi

Taw. The national core group must undergo regular assessment and certification of their competence to ensure that it is maintained.

Table 1: *Core group members and their responsibilities*

Core group (Level)	Participants	Responsibilities
Central level	Deputy Director General (NHL) Director (Laboratory, NHL) Deputy Director (Malaria) WHO responsible person	Technical and Administrative Management
	Head of Department (Parasitology) Assistant Director (VBDC)	Technical, organize, coordinate with two departments, manage and funding agency
	Medical Technologists (VBDC) Lab Technicians (Grade I, VBDC) with (WHO accredited Level 1 or 2)	Trainer, cross-checker, monitor, validator and supervisor. Take part in reporting and feedback with proper data management system
State/Regional level	Director (Public Health) Director (Medical Services)	Administrative Management
	Assistant Director (VBDC)	On behalf of two directors-administration & coordination
	Pathologist/Microbiologist Lab Officer Medical Technologist (Hospitals)	Consultancy Joint M&E
	Medical Technologist (VBDC) Lab Technician Grade I (VBDC) with (WHO accredited Level 1 or 2)	Cross-checker, validator, supervision & monitoring Take part in reporting and feedback with proper data management system

(a) Central Level

The central level plays a key role in providing technical support in the delivery of malaria diagnostic services at all levels, as well as being responsible for the planning, implementation, training and monitoring of QA. It is important that a competent laboratory is designated as the Malaria Reference Laboratory (MRL).

(i)National Health Laboratory (NHL)

In Myanmar, hospitals at different levels have laboratories of different categories (Type A, Type B and Type C) for diagnosis of different diseases including malaria. The National Health Laboratory (NHL) has conducted QA/QC programme of all laboratories and laboratory tests performed at different levels of hospital laboratories. QA for malaria diagnosis is a small component within the NHL QA/QC system, which the NHL and the National Malaria Control Program (NMCP) agreed to strengthen and update. Currently, the NHL send a set of slides which include 2 malaria slides (1 unstained and 1 stained) to various levels of hospital laboratories from central to township level (88 hospitals) for reading in order to assess

performance of laboratory technicians. In addition public and some military hospitals also implement quarterly slide cross-check system where hospital labs have to send stained slides with results to NHL and then send back the results with comments on results, smear, staining & *etc.* NHL should take part a role in international contacts as well as recognition as COE. In 2017, NHL has planned to extend 14 out of 18 VBDC laboratories for EQAS system through proficiency testing.

(ii)National Malaria Control Programme (NMCP/VBDC)

All laboratory staff of the NMCP/VBDC have been trained on advanced courses on malaria microscopy and they also have long term experience on it. Among them, there are 12 technicians undergoing external competence assessment (ECA) and they certified as WHO level 1 in 2016. They are eligible to be a validator, trainer or facilitator for malaria microscopy quality assurance system. Central VBDC has planned to implement PCR program for culture and serology of malaria parasite and also extend to implement malaria slide bank for the whole country. Moreover, VBDC office at Gyogone, Yangon will be planned to promote as a NMRL and it will be used as a training center and QA for malaria microscopy in Myanmar. NMRL will continue to do the cross-checking of the VBDC laboratories and will also expand the cross-checking to the hospitals under the Department of Medical Service.

(iii) National Malaria Reference Laboratory

The NMRL should be responsible for establishing national standards for:

- Training courses;
- Slide Bank;
- Preparation/adaptation of training materials according to local situations;
- Assessment of competency and performance of microscopists according to international standards;
- Accreditation of microscopists; and laboratory procedures and equipment;
- NMRL could also be the focal point for international contacts;
- Strive for international and regional recognition as a centre of excellence.
- Monitoring and supervision of malaria laboratories
- Planning and oversight supplies management system of malaria laboratories

(b) State/ Regional level

Medical Technologist or Senior Laboratory technician of Expert/ Reference level who will implement QA/QC activities and supervised district, township and Station hospital.

Laboratory technicians at State/Regional VBDC should be responsible for the improvement of the quality of laboratories at District, Township and Station Hospital. They are responsible for:

- Supervision and monitoring of activities (Malaria QA)
- Cross Checking of slide
- Provide the feedback of results;

- Take part in reporting and feedback with proper data management system
- Plan and implementation of training and retraining activities within State/Regional level;
- Ensure that equipment is maintained in good working order and that there are no breakdowns in the supply-chain.

(c) District/Township and Station Level

Hospital Technician (Grade I/II) who performed routine malaria diagnosis services will need to follow SOP for Malaria Microscopy in mentioned in the QA guideline.

Malaria must be diagnosed by microscopy for outpatients and inpatients at the township and district hospitals. Therefore, hospital laboratories are required to have the QA system. Apart from township laboratories, malaria microscopic facilities are established in some Station Hospital and strategic points and those are also to be included in QA system.

- Maintain appropriate laboratory records of slide registry log and results, and inventory stocks of supplies and equipment;
- Perform regular assessment and estimation of reagents and stocks to ensure continuous services for patients;
- Provide timely feedback of test results to patients or clinicians;
- Follow QA protocols as recommended.

2.1.2 Job Description of Technologists and Technicians

(a) Duties of a Laboratory Medical Technologist

1. To supervise laboratory staff under his/her charge.
2. To perform special test and when, necessary to perform routine laboratory tests.
3. To prepare special reagent and standards and to supervise and check the reagents and standard prepared by the junior staff.
4. To participate or assist in the training and research activities in his/her lab.
5. To be responsible for the cleanliness, maintenance and timely repair of equipment in his/her charge.
6. To be responsible for timely and proper performance of laboratory tests, maintenance of register records and complication and dispatch of report in his/her laboratory or section.
7. Preparation of annual indents and monthly indents.
8. To keep in charge of Medical sub-store.
9. To be responsible for internal blind cross-checking of routine malaria microscopy slides and internal quality control if he/she already has **malaria microscopy QA training.**
10. To be responsible for checking of data management of recording, reporting, data storage and analysis of routine and crosschecking data.
11. To perform other duties delegated by his/her superior and where required, will be in-charge of the Laboratory or Section in the absence of the supervisor.

(b) Duties of a Laboratory Technicians Grade (I)

1. To manage lab, reception, collection, preparation, and storage areas.
2. To examine specimens, record and report.
3. To prepare standard solution, reagents for analysis.
4. To maintain laboratory registers and records at reception and for equipment, chemical and reagent, furniture etc.
5. To care and maintain lab equipment, apparatus, glassware, chemical and reagent including lab furniture.
6. To perform available laboratory tests including malaria microscopy under the supervision of MO / Lab in charge or Pathologist or Technologists.
7. To prevent lab accidents by safe disposal of infected materials and cleanliness of lab etc.
8. To assign the duties to his subordinates.
9. To dispatch lab specimen to Central lab /Divisional Lab etc.
10. To prepare annual and monthly indents, and prepare monthly and annual lab reports.
11. To perform other duties delegated to him/her by his/her superiors and when required will be in charge of the lab or section instructed to him/her.
12. To be responsible for internal blind crosschecking of routine malaria microscopy slides and internal quality control if he/she already has **malaria microscopy QA training.**

(c) Duties of a Laboratory Technicians Grade (II)

1. To receive, collect, prepare and store specimens.
2. To prepare reagents required for basic analysis.
3. To perform basic laboratory tests including malaria microscopy under the supervision of Pathologist or M.O lab/ Medical Technologist / Grade I technicians.
4. To care, maintain and clean the lab apparatus and equipment.
5. To maintain the lab registers and data entry.
6. To keep the laboratory clean.
7. To perform other duties delegated to him/her by his/her supervisor (M.S, Pathologist, Medical Technologist or Grade I Technician.
8. To be responsible for internal blind crosschecking of routine malaria microscopy if he/she is only one microscopist in his/her respective health facility.

3. PLAN OF ACTION

3.1 Objectives of Quality Assurance

QA programmes should prepare a national QA manual or guideline to:

- To improve the overall performance of microscopists at each level of the laboratory services
- To obtain the highest level of accuracy (sensitivity & specificity) in confirming the presence of parasites
- To monitor laboratory procedures, reagents and equipment used in a routine practice
- To establish a clear hierarchical reporting system for the results of QA and feedback.

3.2 Essential Elements of the QA

The main elements of a plan of action for a laboratory QA system are:

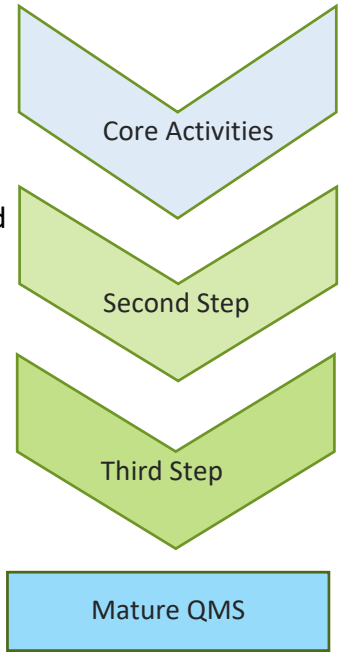
- Alignment with the priorities of the National Health Laboratory (NHL) services and the NMCP;
- A “gap analysis”;
- The specific objectives and goals of the programme;
- Expected outcomes;
- Constraints that might affect achievement of the objectives and goals;
- Activities to be conducted;
- A timetable;
- A detailed, realistic budget;
- A list of indicators for measuring the progress and outcomes of the programme, with appropriate reporting forms; and
- Clear roles and responsibilities for key personnel.

3.3 Phases of QA

Effective QA should be conducted in a phased approach according to priorities. The colours in the illustration below indicate the order in which activities should be introduced to achieve a mature quality management system.

Core activities

1. Make a baseline situation analysis of the resources available in the country and gaps in commodities and infrastructure.
2. Identify the QA coordinator and a national core group of technicians undergoing external competence assessment (ECA) and certified as WHO level 1 or 2.
3. Establish a national steering committee of Malaria Control Programme
4. Ensure policies, guidelines, SOPs and associated commodities and infrastructure.



Second step

5. Competence assessment
6. Training
7. Supervision

Third step

8. Cross-checking
9. Proficiency testing
10. On-site evaluation
11. Accreditation of the diagnostic centre to international Standards such as ISO 9001:2008, ISO 15189:2012 or ISO 17025:2005

3.3.1 Situation Analysis

A situation analysis should be done to determine the current status of QA in the country by the following tasks.

1. Make a chart of the laboratory network, showing relations and functions of different Levels
2. Make an inventory of the available resources (staff, microscopes, equipment and budget)
3. Collect data on the current workload, and assess the adequacy of resources with respect to the workload.
4. Document all current QA activities, including QC. Collect data and evaluate performance. Identify limitations and causes of problems such as unsustainability.
5. Assess the competence of technicians at all levels of the programme.
6. Determine the resources that are available and required for implementing or extending QA.

   The factors that determine effective implementation of a QA system are:

   - The objectives of NMCP and the role of parasitological confirmation of malaria;
   - Current laboratory services for malaria diagnosis;
   - The status or feasibility of integration with NHL (depending on the objectives of the NMCP);

- The role and importance of the private sector and NGOs in malaria diagnosis and treatment;
- The existence and capacity of the NMRL;
- The capacity of existing infrastructure and staff for training and for assessing the competence and performance of laboratory services;
- Current availability of reagents and equipment;
- Capacity of existing logistic systems to ensure provision of the necessary reagents and equipment and maintain the equipment in working order;
- The availability and use of guidelines and SOPs to ensure the quality of all aspects of malaria microscopy;
- Reporting mechanisms; and
- Current organization, status and performance of QA and current levels and sources of financial support for strengthening malaria diagnostic services.

3.3.2 Workload

Excessive work is a major factor in poor performance. The sensitivity of diagnosis is directly related to the time available to examine blood films; it therefore decreases when the number of slides exceeds the work capacity of the technician.

It is now widely accepted that no more than 30–40 slides can be effectively read per day. Annex – 1 Malaria microscopy registration form for routine register and crosschecking

Table 2: *Estimated times for calculating the minimum total time required to examine a thick blood film for malaria parasites (slide is of good quality)*

Activity	Minimum Time Required
Locating and placing the slide on the microscope stage	5 s
Focusing x10, then adding oil and focusing the x100 objective	10 s
Microscopic examination of a high-density positive thick film to determine positivity or negativity	10 s
Microscopic examination of a low-density positive thick film to determine positivity or negativity	2–6 min
Microscopic examination of a negative thick film	6 min
Counting of the number of parasites/200 WBC in a positive film	10 min
Recording the result in a register	20 s

The number of slides that can be examined also depends on whether the technician:

- performs only microscopy or has additional duties;
- only stains and examines the films; or
- performs all the functions necessary to obtain a microscope diagnosis (collecting blood from the patient, preparing and staining the blood films and examining them under a microscope).

4. SUPPLIES AND EQUIPMENT

4.1 Standard lists

High-quality work depends directly on the quality of the equipment, reagents and other consumables. Guidelines on requirements for Malaria Microscopy should include:

i. A list of the minimum standards and specifications for equipment and supplies,
ii. Recommendations for selecting microscopes and
iii. Guidelines for assessing microscopes used in the field to ensure that they operate correctly.

Standard lists of all the equipment and supplies including spare parts should be set at country level. Annex 2. Reagent and equipment list of Malaria Microscopy

4.2 Establishment of a supply Chain

An effective supply chain management system must be established in order to foresee needs and ensure the provision of all the equipment and supplies required for uninterrupted, reliable laboratory diagnostic services for malaria. An inventory management system should be created for equipment, including spare parts, reagents and supplies.
Standard procedures should be in place for routine assessment of levels of consumption and of stocks of key reagents, supplies and spare parts for microscopes.

4.3 Microscope

A reliable, well-maintained microscope is an essential requirement for accurate malaria microscopy. A binocular microscope with x10 eyepiece, an oil immersion lens (x100) and a built-in electrical light source is essential. The use of blue filters to increase resolution and change the light from that of ordinary electric bulbs to a more natural white light is also recommended.
To increase the life-span of microscopes, preventive maintenance, including cleaning the objectives and replacing parts as necessary, should be part of routine internal QC and must be properly recorded and documented. Microscopes should be covered when not in use to avoid exposure to dust, and proper precautions must be taken in humid areas to avoid fungal growth on the lenses and in the microscope.

4.4 Microscope slides

Only high-quality microscope slides, a frosted end labelling, free of surface abrasions and purchased from a reputable supplier should be used for malaria microscopy. The slides should

be scrupulously free from grease, moisture or fungus and should therefore be cleaned and stored before use.

It is recommended that slides not be re-used.

4.5 Staining reagents

Many differential stains have been developed for the detection of malaria parasites.

The alcohol-based Giemsa stain is the "gold standard". It is the one most commonly used and the best for routine diagnosis because it can be used for both thick and thin blood films, is stable during storage and results in a constant, reproducible quality of staining at a range of temperatures. One of the critical variables in staining is the pH of both the staining solution and the water used for washing.

Simple hand-held pH meters should be available in all malaria diagnostic laboratories, as pH paper is not accurate enough for measuring the pH of water and buffers. Small differences in pH (such as between pH 7.0 and pH 7.2 or pH 6.5 and pH 7.0) can significantly affect stain quality.

4.6 Other supplies

High-quality microscopic diagnosis of malaria requires a continuous supply of other commodities including timers, markers, lancets, syringes, needles, Vacutainer-type needles, alcohol swabs, oil immersion lens-cleaning solution, lens-cleaning tissues, buffer tablets, pH calibration solutions, cotton-wool, gloves, safety glasses (including the over-spectacle type), filter paper and glycerol. Safety items such as gloves, sharps boxes, gowns and detergents, should always be available. In order to store standard slides for internal QC or to store patient slides for an external QA by a peripheral, intermediate or national programme, slide boxes should be available in any health facility that provides microscopic diagnosis of malaria.

Fuses and bulbs are relatively inexpensive and easy to replace. The availability of spare bulbs and fuses in a laboratory in which primarily microscopy is used for testing could determine whether a case is confirmed as malaria and should be a priority for procurement.

Annex – 3 Stock Book, Annex – 4 Stock request form, Annex – 5 Stock supply form (samples)

5. INTERNAL QUALITY CONTROL (IQC)

5.1 Internal quality control

Internal QC is the daily control and monitoring of each stage of testing by laboratory personnel to ensure that all tests are performed accurately and precisely. Internal QC affects all the steps taken in routine laboratory procedures to ensure good quality results. All laboratory staff should use it to check their performance and to ensure the reproducibility and sensitivity of laboratory diagnoses. The head of the laboratory is responsible for establishing internal QC in routine procedures, but all personnel must be involved and participate. A technician working in isolation should also routinely conduct internal QC, although the number of checks is more limited.

Internal QC is embedded in all laboratory procedures and is a continuous process. Its objective is to provide reliable results at all times.

5.2 Implementation

Procedures/Steps for internal QC should be initiated immediately in diagnostic centres. The steps could be as follows:

1. Establish written policies and SOPs.
2. Assign responsibility for monitoring the policy and use of SOPs.
3. Train staff.
4. Obtain control materials.
5. Collect data.
6. Set target values and results.
7. Analyse and display control data regularly.
8. Establish and implement problem-solving and corrective protocols.
9. Establish and maintain a system for documentation.

Effective internal QC requires a "culture of quality" in laboratories, whereby staff understand the concept and use of internal QC.

5.2.1 Recommended routine activities

Each day. Stained QC slides should be used to check the quality and performance of the Giemsa stain. Malaria-positive blood should be used to prepare QC thick and thin films, which are then stored (for up to 2 weeks in a cool, dark, dry area) and stained at the same time as the next batch of patient slides. Before examining the stained patient slides, the QC slides are checked for the quality of blood components. If the QC slides are satisfactory, the patient slides can be examined with confidence.

Each week. All staff should jointly review problematic slides encountered during the week, and a selection of slides from each technician should be rechecked by the head of laboratory or by cross-checking among staff.

Slides must be selected regularly for cross-checking, either by sending them to a crosschecking centre or during routine supportive supervisory visits. Cross-checking in the

laboratory should be organized by ad hoc structured, blinded checking of slides with unusual or uncertain aspects, followed by discussion between the validator and the technician. In most laboratories, both senior and junior technicians should be involved, and all laboratory staff should work as a team. When an error is identified, the validator should review the slide with the technician, who should take corrective action, such as filtering or replacing poor-quality Giemsa stain.

Basic technical aspects that should be monitored regularly include:

- use of equipment, especially the microscope and its condition;
- the quality of reagents and stains, including storage conditions;
- the pH (7.2) of the buffer;
- accurate use of SOPs by laboratory staff;
- detection and recognition of parasites; and
- accurate completion of the laboratory register, logs, result work-sheets and internal QC records.

5.3 Corrective action

The main benefits of internal QC are early recognition of problems and swift corrective action, which must be taken whenever non-conformity is identified by internal QC.

Technical processes must be available to make corrections, with effective means to prevent recurrence, such as adjusting the microscope stage, cleaning the objective, filtering or replacing stain and correctly storing stains and supplies. These actions are the basis of continuous quality improvement.

Internal QC procedures must be checked regularly during supervision visits by technical staff.

5.4 Measuring the impact of internal quality control

Indicators that can be used to measure the impact of internal QC include:

- Laboratory **registers** or logs and internal QC **records** kept according to relevant SOPs;
- Rates of **corrective action**;
- The **reliability** of laboratory results, whereby a clinician can establish a rapid, correct diagnosis;
- **The reputation** of the laboratory;
- **The motivation** of staff; and
- **Accreditation** of laboratories.

6. TRAINING

6.1 Training Courses in Malaria Microscopy regularly conducted in Myanmar

1. Basic Malaria Microscopy Training/ New Training for Basic Health Staff (BHS)
2. Capacity Building of Malaria Microscopist/ Refresher Training for all technicians
3. E-training and E-assessment (Not implemented now)

Note: Grade II students in State/Region will be trained malaria microscopy at State/Region VBDC laboratory. Grade I students who attend training at NHL will be trained malaria microscopy bloc positing at VBDC, Gyogone.

***Table 3**: Selection criteria and training requirements for malaria microscopists*

Trainee	Selection criteria	Training
Person with no previous experience (Basic Malaria Microscopy Training)	Can read and write at a basic level If difficulties are found during training, test eyesight.	Minimum 5 weeks at a level at least equal to the WHO training course Practical and theoretical examination
Laboratory technician (Capacity Building of Malaria Microscopist)	Experience in microscopy in a laboratory	Minimum 2-week training course Practical and theoretical examination

***Table 4**: Minimum competence levels for peripheral level microscopists*

No	Competence	Result
1	Sensitivity: Proportion of positive slides correctly read as positive	90%
2	Specificity: Proportion of negative slides correctly read as negative	80%
3	Accuracy of reporting P. falciparum when present	95%

6.1.1 For National Core group

In order to become national core group member, the following additional training has been conducted and accomplished;

a. National Competency Assessment (Level A)

b. External Competency Assessment (Level 1 & 2, Expert and Reference)

***Table 5**: Basis for determining competence levels in a national competence assessment (NCA)*

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

***Table 6**: Interim grades for final competency assessment for expert accreditation External Competency Assessment (ECA)*

Competence level (Grade)	Parasite detection (%)	Species identification (%)	Parasite count within 25% of true count (%)
1- Expert	90 - 100	90 - 100	50 -100
2. Reference	80 -89	80 -89	40 -49
3. Advanced	70 -79	70 -79	30 -39
4. In training	0 -69	0 -69	0 -29

6.1.2 Responsibilities of core group members

1. The national core group must undergo regular assessment and certification of their competence to ensure that it is maintained.
2. An external competence assessment of national core group microscopists is usually conducted by an external assessor who is a highly trained, competent microscopist skilled in assessments.
3. Trainer competency training and a SOP development
4. Instructional skill development

6.2 Method of Training

Training courses for microscopists are conducted by using syllabus detailed in the WHO training manuals, Basic malaria microscopy part 1; Learner's guide and basic malaria microscopy, part 2; and the Tutor's guide (2010).

6.2.1 Training Requirements

1. Standard SOP on Training (WHO training manual)
2. Standard slide sets
3. Standard lecture manual
4. Standard laboratory procedure
5. Standard grading
6. Microscopes
7. Multiview microscope

8. Projector
9. LCD
10. Flip Chart
11. Malaria microscopy laboratory equipment including stain.

6.3 Refresher training

Refresher training is considered essential for maintaining the competence and commitment of microscopists. It is recommended that:

- anyone performing malaria microscopy have refresher training every year,
- refresher courses should last a minimum of 1 week, and
- refresher courses should include more stringent training on species identification and quantification.

***Table 7**: Interpretative Guide on Grading System for refresher training*

Overall Rating	Description
80% and above	PASS
79% and below	FAIL

***Table 8**: Detailed explanation on grading score for refresher training*

Overall Rating	Interpretation	Recommendation
80% and above	The trainee passed the minimum requirement of this assessment to perform malaria microscopy.	Trainee to undergo refresher training every 1 yrs or next step to competency assessment. Participate in IQC and EQA program for malaria
79% and below	The trainee failed to meet the minimum requirement of this assessment to perform malaria microscopy.	Trainee will perform malaria microscopy but will be reassessed through panel testing within 3months in addition to the mandatory submission of slides for validation. Retraining or refresher training after 2 poor performance in panel testing within a year. Participate in IQC and EQA program for malaria.

6.4 Retraining

If a technician's performance is considered poor on the basis of slide cross-checking and proven to be due to incompetence during supervisory visits, the actions listed below should be taken.

- Additional supervisory and mentorship visits should be arranged for corrective training.

- The technician should be given two or three opportunities to improve performance.
- As appropriate, **formal retraining should be provided** (such as attending a further training course).
- The technician's eyesight should be checked.

If the technician fails to improve, he or she should not be permitted to examine and report on malaria slides.

6.5 Reporting

Comprehensive, effective training is an important component of an effective malaria microscopy QA system, and the outcomes must be reported regularly. When assessing QA, the availability of good training and assessment must also be checked during visits by technical staff from supervisory laboratories.

6.6 Corrective action

One of the main benefits of effective QA is early recognition of problems and swift corrective action. Corrective action must be taken when any non-conformity is identified in the training or assessment system. Deficiencies identified in the training programme should be corrected and effective mechanisms introduced to prevent their recurrence.

This action will be the basis for continuous improvement of quality.

6.7 Measuring the impact of training

Indicators that can be used to measure the implementation and impact of training include:

- reports of participant satisfaction;
- evidence of an effective training programme (such as schedule and timetable);
- up-to-date records of training in the technician's folder;
- evidence that procedures are being performed correctly;
- better accuracy and reliability of laboratory results, thereby helping clinicians to establish the proper diagnosis rapidly, leading to better management of patients; and
- Achievement of certification in NCA and ECA programmes.

6.8 E-training and e-assessment

Recently, NMCP try to use Google Drive system for assessing laboratory quality assurance via e-assessment questionnaires forms. This method will be widely used in all State/Region of Myanmar.

7. CROSS-CHECKING MALARIA SLIDE RESULTS

7.1 Objective of cross-checking

Cross-checking is an important component of effective QA. It indicates whether a laboratory is providing accurate results and can detect major deficiencies in laboratory performance due to level of competence, poor equipment, poor reagents, poor infrastructure or poor work practices.

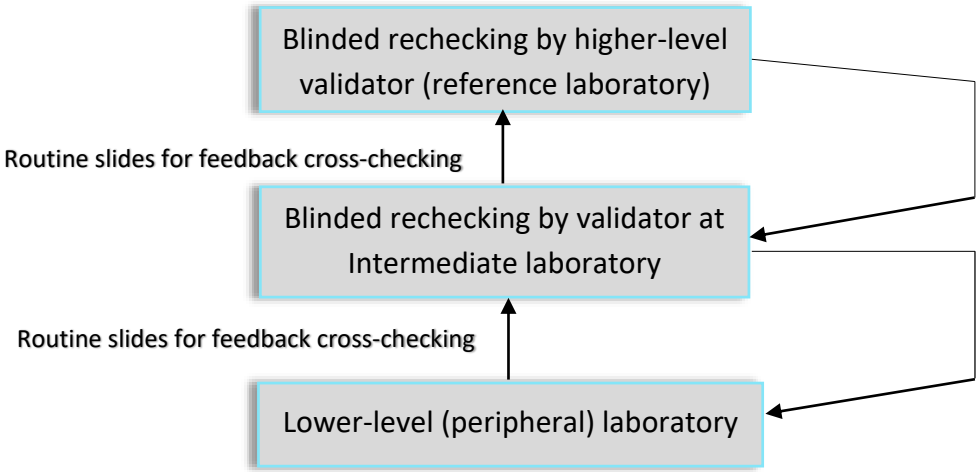
It is essential and may be done either at a cross-checking center (VBDC) or at regular supervisory visits to the technician's workplace.

7.2 Principles and classification of errors

External QA by cross-checking is based on blinded re-examination of a selected sample of slides by staff at a higher-level laboratory. The validator undertaking re-examination must be highly skilled in malaria microscopy, have a thorough understanding of the sources of error and be able to compile the report that will be returned to the peripheral laboratory. Re-checking must be done by certified malaria technicians of proven competence. The microscopes used by the validators must be of good quality and in good condition.

Problems detected by the validator should be noted on the report form, as this information may be useful for supervisors responsible for providing feedback to peripheral technicians, determining the reasons for error rates and planning retraining and corrective action.

Figure 3 – Organization of slide cross-checking



Cross-checking must be blinded to ensure objectivity; i.e. the validator who rechecks a slide must not know the initial result. Once a slide set has been examined and discrepancies are identified (differences between the clinical technicians and the validators), the validator should recheck the discrepant slides with a further, un-blinded reading to confirm that there is no error, before reporting the result as discrepant.

The peripheral laboratory must be informed as soon as possible when a discrepancy is found between the reported result and that found by rechecking. The controlling laboratory should

give feedback when appropriate, including probable explanations of the discrepancy and suggestions for corrective action. The results should be recorded in a database, which must be available to the supervisor before the next supervisory visit, at which discrepant results and the probable explanations must be discussed.

7.3 Common causes of errors in blinded slide rechecking

Table 9: Common possible causes of errors in blinded slide rechecking

Initial laboratory true (+)ve - cross-check false (-)ve	Initial laboratory true (+)ve - cross-check false (+)ve	Initial laboratory true (-)ve - cross-check false (-)ve
Very low parasite density	Laboratory staff report negative slides as "weakly positive" because they consider this "safer"	High workload, so that technicians examine slides too quickly
Stain faded since original examination	Artefacts such as stain deposit or unfiltered water incorrectly interpreted as malaria parasites	Poor skill level of laboratory staff
Too high a QC workload for the validator	Howell-Jolly bodies and platelets misidentified as malaria parasites	Poor staining technique
Poor skill level of validator	Poor skill levels of laboratory staff	Clerical error
Pressure on laboratory staff to find malaria parasites when there is a clinical suspicion of malaria	Clerical error	Poor skill level of the validator

- Training/validation for Expert/ Reference level microscopists at the Central and State/Region level
- Refresher training on QA/QC protocols for State/Region Senior Microscopists (Annually)
- Refresher training on QA/QC protocols for microscopists (minimum training every 2 years, or more frequent depending resources and situation analysis)
- On-site training/On-job training during routine monitoring and supervision visits (OTSS)

7.4 Method for slide cross-checking

The method and protocol are based on:

- Minimal sample selection
- Selection of weakly positive slides
- Accurate cross-checking
- Rapid availability of QC results
- Valid statistical analysis of results and

- Central reporting and analysis of results

This protocol is applicable for laboratories and test centres for routine diagnostic malaria microscopy. The same sample size is not applicable for QC of blood slides taken for research purposes.

7.4.1 Slide storage

All routine slides examined by a laboratory must be stored in secure slide boxes protected from excessive heat and humidity until the QC slides have been selected.

Slides must be stored consecutively according to the laboratory identification number.

The stored slides should be free of immersion oil, and the laboratory number should be clearly visible; the results of examination of the blood film should not be written on the slide. Routinely prepared slides must not be discarded until the QC slides have been selected.

7.4.2 Sample selection from the laboratory register

QC depends on correct selection of the sample. The three critical determinants are

1. the method of selection (random or systematic, with no opportunity for selection bias),
2. the minimum sample size
3. the selection criteria
   - QC sample must be selected from the laboratory register.
   - Microscopy slides for cross-checking must not be selected directly from slide storage boxes.
   - When the number of tests performed is less than the minimum sample size, all slides must be cross-checked.

The laboratory supervisor is responsible for randomly selecting a minimum of 10 slides each month (five reported as low-density, five reported as negative) for QC, using a random numbering system. If a random numbering system cannot be generated, selection should be based on random or systematic sampling independent of the microscopist(s) being checked. It is important that QC slides be selected randomly from routine tests performed during the calendar month or more recently (see below).

Therefore, routinely prepared slides must not be discarded until the QC slides have been selected.

Five weakly positive slides with a parasitaemia of 20–200 trophozoites/µL and five negative slides should be selected. Slides with parasite densities > 200 trophozoites/µL should **not** be selected.

To avoid selection bias, a clear selection protocol must be established in the SOPs, based on a random selection from a list of all low-density positive slides and all negative slides.

Remark: If the number of malaria slides tested within one month is under **30**, all tested slides must be sent to respective State/Region VBDC for cross-checking. If the number of tested slide is more than 30, the above procedure can be followed.

For low transmission areas, all positive slides and 20% of negative slides should be sent if tested slides are more than 30.

7.4.3 Accurate cross-checking

Laboratories are encouraged to perform more QC than the minimum requirement, **provided** that there is sufficient capacity for all QC slides to be cross-checked accurately.

(a) Timing

Cross-checking should be done as soon as possible after the end of each month and the feedback results reported optimally within 2 weeks.

An important principle of the QC protocol is that the results are an integral part of laboratory management and must be available and analyzed as soon as possible.

(b) Selection of cross-checker (validator)

QC depends on accurate cross-checking of QC slides. Validators or cross-checkers must have proven competence (e.g. WHO-certified level 1 or 2) within 3 years. The validators must be enrolled in an external QA program with some form of internal or external cross-checking.

(c) Accuracy

Slides must be cross-checked with considerable care. The accuracy of cross-checking is expected to be higher than that of routine slide-reading.

Low sensitivity in routine examination is frequently due to variables such as high workload and poor equipment and not to lack of skill of the reader.

7.4.4 Recording results

All results should be recorded in a 2x2 table, as follows:

(i) QC monitoring based on identification of asexual blood parasite stages

Routine laboratory result	Cross-check	
	Positive	**Negative**
Positive	A	B
Negative	C	D

A = the number of slides reported as positive by both readers (true positives);

B = the number of slides reported as positive in routine testing by the laboratory but found to be negative by the cross-checker (false positives);

C = the number of slides reported as negative in routine testing by the laboratory but found to be positive by the cross-checker (false negatives); and

D = the number of slides reported as negative by both readers (true negatives).

$$\text{Percentage agreement in parasite detection} = \frac{(A + D) \times 100\%}{A+B+C+D}$$

(ii) QC based on monitoring the accuracy of differentiation of *P.falciparum* and non-*P.falciparum*

Laboratory	Cross-checking	
	***P.falciparum* present**	***P.falciparum* not present**
P.falciparum present	A	B
P.falciparum not present	C	D

A = the number of slides reported as containing *P.falciparum* by both readers;
B = the number of slides reported as containing *P.falciparum* only in routine testing by the laboratory but not confirmed by the cross-checker;
C = the number of slides reported by laboratory as not containing *P.falciparum* in routine testing but *P.falciparum* found to be present by the cross-checker, as a single or a mixed infection; and
D = the number of positive slides reported as not containing *P.falciparum* by both readers

$$\text{Percentage agreement in parasite detection} = \frac{(A + D) \times 100\%}{A+B+C+D}$$

Annex –6 Format used for dispatch of slides for crosschecking and feedback

7.4.5 Statistical analysis

QC results should be analysed monthly and in a progressive 4-month cohort analysis. The analysis
and reporting of the results of cross-checked slides should be standardized to avoid misunderstanding between validators and those whose performance is being checked.

Monthly analysis of QC results

Individual monthly results should be evaluated for any major errors, to allow rapid feedback. Because of the small sample size, however, the result will not necessarily reflect the true overall performance of the laboratory:

- There may have been an exceptionally high workload, a problem with a reagent or a new staff member at the laboratory during the month, which should be reported centrally.
- Errors are not necessarily evenly distributed, and there may have been more errors than usual during a particular month; this may be balanced by a lower than normal error rate in another month.
- A limitation of a sample size of 10 is that single errors significantly affect the calculated percentage agreement. Hence, a single error in 10 QC samples will reduce the agreement to 90%.

Interpretation of individual monthly results should take into account the previous performance of a laboratory or test centre. The following may be used as a guideline.
When the previous QC results have been good to satisfactory

- **Two errors out of 10 results is an alert.**

- **Three or more errors out of 10 results require immediate investigation.**

$$\% \text{ Agreement} = \frac{(\text{True Positive} + \text{True Negative}) \times 100}{\text{All slides examined}}$$

$$\text{Sensitivity} = \frac{\text{True Positive} \times 100}{\text{True Positive} + \text{False Negative}}$$

$$\text{Specificity} = \frac{\text{True Negative} \times 100}{\text{False Positive} + \text{True Negative}}$$

When the previous QC results have been poor

- A result that is better than previous results is encouraging.
- A persistently static or a progressive decrease in the percentage agreement indicates that ***corrective action has not been effective and should be reviewed*.**

***Example**: In a laboratory in which QC is performed on 10 samples per month:*

Month	No. of errors	Monthly agreement	Progressive agreement
January	0	100%	Too few samples
February	1	90%	Too few samples
March	0	100%	Too few samples
April	1	90%	95%
May	3	70%	85.5%
June	0	100%	90%
July	1	90%	87.5%
August	0	100%	90%
September	1	90%	95%
October	0	100%	95%
November	1	90%	95%
December	0	100%	95%

Thus, a single poor result in May affects the progressive 4-month analysis for the period May to August. This disadvantage of cohort analysis applies irrespective of whether it is a progressive or a fixed-period analysis. With the above data, the same distortion occurs when the data are analysed in three fixed periods; for example:

- January–April: insufficient data
- May–August: 90%
- September–December: 95%

Calculation of the true false-positive rate

The true false-positive rate is calculated on the assumption that there is little probability that strongly positive slides are false positives. If a blood film is reported by a laboratory as being strongly positive but found to be negative on cross-checking, this probably represents a clerical error rather than a technical reading error.

To calculate the true false-positive rate, laboratories and test centres must record the proportions of strong and weak positives reported in the period of the analysis:

True false-positive rate =

$$\frac{\text{Percentage of false-positives x total number of weakly positive blood films}}{\text{Total number of positive blood films}}$$

Example: Over 4 months, a laboratory reports 500 positive blood films, comprising 450 strongly positive and 50 weakly positive results. During the same period, 20 weakly positive thick films are randomly selected for cross-checking (five each month), and two are found to be negative.

The false-positive rate = 2/20 = 10%. As the total number of weak positives in this period is 50, by extrapolation, the estimated number of false-positive thick films = 5 (10% of 50). It is assumed that all strong positives are true positives (or clerical errors). The total number of positive slides in this period is 500. Therefore, the calculated true false-positive rate = 5/500 = 1%.

7.4.6 Reporting results

Monthly QC results should be reported to the QC supervision with 2 weeks of the end of the calendar month in which routine testing was performed. Results should be reported on a standard QC reporting form. (Annex-1)

7.5 Corrective action to be taken in the case of discordant results

One of the main benefits of effective QA is early recognition of problems and swift corrective action. Corrective actions must be taken whenever nonconformity is identified by cross-checking. If deficiencies in the cross-checking programme are identified, technical corrections and effective mechanisms to prevent recurrence must be introduced. This will ensure continuous quality improvement.

If the laboratory staff who performed the initial testing consider that the cross-checked result is incorrect, they should be given the opportunity to re-examine the slide or sample. Thus, microscopy slides sent to a reference laboratory for cross-checking and found to be discordant should, if possible, be returned to the routine laboratory after examination.

When cross-checking is performed by people with competence similar to that of the staff who performed the initial testing, any discrepancies should be reviewed by the original laboratory.

- If the laboratory that performed the initial reading agrees with the result of cross- checking (that the original reading was erroneous), the cross-check result can be accepted. This must be recorded as an error in the QC analysis.

- If the laboratory that performed the initial reading disagrees with the result of cross-checking, the slide or sample should either be re-examined by the cross-checker or referred to a third reader. If the cross-check result is found to be erroneous, the original result should be recorded as correct in the QC analysis.

7.6 Measuring the impact of cross-checking malaria slide results

Indicators that can be used to measure the impact of cross-checking of malaria slide results include:

- evidence of an effective laboratory cross-checking programme (such as schedules and results);
- up-to-date cross-checking records and feedback kept at the diagnostic facilities;
- improved accuracy and reliability of laboratory results over time; and
- evidence of an improving laboratory measurement system.

8. EXTERNAL QUALITY ASSESSMENT SCHEME (PANEL TESTING)

The term “external quality assessment” is used to describe a method by which an individual or body outside the laboratory, often the supervisor or governing authority, assesses a laboratory’s testing performance. This can be compared with the performance of a peer group of laboratories or a reference laboratory.

Parasitology Section of National Health Laboratory (NHL) established the National External Quality Assessment Scheme (NEQAS) for Malaria Microscopy in 2007. It was gradually extended and a total of 88 laboratories have been participating since 2011.

8.1 Panel testing

In the panel testing, participating laboratories examine a set of prepared slides received from the central reference public health laboratory, Parasitology Section of NHL, in order to gauge the ability of technicians to recognize, identify and count malaria parasites on the reference slides. Inter-laboratory comparisons are an important component of regular external quality assessment of a laboratory’s performance. NHL distributed those proficiency samples biannually, consisting of 2 blood-smeared slides (1 unstained and 1 stained slide). Annex – 7 Request and report form for panel testing, Annex – 8 Results for the EQAS

8.2 Assessment of the performance of participating laboratories

For the assessment of the performance of the participating laboratories, reported results from participating laboratories were assessed using following scales (Table 1). Scoring of malaria microscopy is based on the identification of malaria parasites, species, stages and density of *Plasmodium* species. The maximum score for each slide is 4 points.

Table 10*: Scoring of panel slides for proficiency testing from National Health Laboratory*

Diagnostic criteria	Points per slide
Positive slide reported as negative or vice versa	0
Positive slide reported correctly as positive	1
Positive slide reported with correct parasite species identification	1
Positive slide reported with correct parasite stage identification	1
Positive slide reported with correct parasite load	1
Negative slide report correctly as negative	4

Feedback and scoring results were sent to each participating hospital after assessing the returned slides and results.

8.3 Participating laboratories

A total of 88 hospital laboratories of Myanmar participated in National EQAS for malaria microscopy including 16 central hospital laboratories, 10 state hospital laboratories, 7

regional hospital laboratories, 21 district hospital laboratories, 32 township-hospital laboratories, and 2 military hospital laboratories.

Objective

- assess the performance of a laboratory in providing accurate results;
- monitor a laboratory's continuing performance over time;
- identify problems or areas for improvement in malaria diagnosis;
- provide assurance to a laboratory's customers that it can provide accurate, reliable results; and
- provide training and educational materials to laboratories.

9. OUTREACH TRAINING AND SUPPORTIVE SUPERVISION (OTSS)

OTSS is a decentralized method of supportive supervision by a team of clinical and laboratory supervisors whose competence has been assessed rigorously. 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, availability and use of SOPs, 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, for supervising the programme, for correcting poor performance identified by cross-checking of slides and for providing strategies and corrective actions for immediate problem-solving.
The reasons for poor competence of technician include:

- inadequate training
- no or little refresher training,
- limited, irregular supervision,
- inadequate and irregular QA (cross-checking and proficiency testing) and
- Infrequent examination of blood films with the decreasing frequency of some parasite species in some regions.

Staff competence is only one of many factors that can affect performance. The most poor examination results are due to:

- poor motivation or personal problems,
- a poorly maintained microscope,
- poor quality or incorrectly stored reagents,
- stock-outs of reagents or other essential items,
- poorly prepared blood films,
- poorly stained blood films,
- poorly labelled blood slides,
- Excessive workload,
- reporting errors
- No updated reference documents such as SOPs and bench aids and
- Lack of regular, sustainable funding for diagnosis.

For RDT OTSS, URC-ADB project continue to discuss with both NMCP and NHL for further field implementation to access the RDT QA at the end users as detail checklist in Annex 12. The following steps are conducted during OTSS for malaria microscopy.

I. Face-face training
II. Reading of standardized blood films
III. An Opportunity of cross-checking ,slide reading
IV. Feedback can be given immediately
V. Providing an opportunity on focus training or revision

VI. Minoring of performance throughout testing

9.1 Implementation

The following components are essential for establishing routine OTSS:

- Involvement of policy-makers and management in planning and executing OTSS, with feedback to secure their commitment, financial support and authority;
- Adequate human resources, including national or regional coordinators, competent supervisors and monitoring and evaluation staff to manage all aspects of the visit;
- Regular training and competence monitoring of supervisors; and
- Adequate funding for visits, feedback meetings and corrective action.

9.2 Method of OTSS

(a)Human Resources

(i)National-level Supervisors

National-level Supervisors are highly competent in Malaria Diagnostics and case management and have extensive experience as trainers and supervisors. They are responsible for training regional, intermediate and peripheral level supervisors and for coordination with managers in the community.

(ii)Regional, intermediate-level and peripheral-level supervisors

Supervisors at these levels are responsible for facilitating OTSS at the health facilities that provide malaria diagnosis and treatment services in their region. Their main role is to mentor health workers and monitor the quality of service over time.

9.3 Checklists for OTSS

A standard checklist is used during OTSS visits to track progress in achieving quality indicators and to monitor the effects of any training provided on site. The checklist should include a review of the findings at the previous visit, an inventory of capacity, observations, mentoring and recommended action.

The observations made on the checklist. Recommendations for corrective action should be made Prompts for supervisors to communicate or reinforce messages can be added to the checklist and changed according to the programme priorities or revised annually.

It is recommended that the following components be monitored routinely:

Annex – 9 Checklist for supervision (OTSS) of Malaria Microscopy Laboratory status

Annex – 10 Accuracy of microscopic examination of blood slides

Laboratory components:

- level and number of laboratory staff;
- training of laboratory staff to diagnose malaria (within the past 12 months);

- water and power supply;
- microscopes, spare parts and maintenance;
- essential laboratory equipment;
- Biosafety;
- stock-outs of essential supplies;
- Reference materials (SOPs, bench aids, national guidelines and policies);
- Procedures for internal QC;
- External QA by slide rechecking and proficiency testing;
- Time for obtaining microscopy and RDT results; and
- Reporting of test results.

Laboratory observations:

- Malaria microscopy:
  - Preparation of thick and thin blood films,
  - Staining of thick and thin blood films,
  - Examination of thick and thin blood films and reporting results
- RDTs: preparation and reading of an RDT.

Clinical components:

- Level and number of clinical staff,
- Training of staff in malaria case management,
- Clinical equipment,
- Stock-outs of essential drugs,
- Stock-outs of artemisinin-based combination therapy and other anti-malaria drugs,
- Clinical documentation and
- Reference material (national guidelines and policies, clinical algorithms and SOPs).

Clinical observations:

- Preparation and reading of an RDT, when relevant;
- Clinical investigation of febrile illness; and
- Adherence to malaria test results in prescribing treatment.

9.4 The OTSS visit

An initial OTSS visit should take 2 days and subsequent visit should take 1 day depend on the size of the health facility, the number of staff, the number of supervisors per health facility and the extent of integration with other external QA schemes (e.g. proficiency testing) or disease programmes.

OTSS visits are dynamic, even though the checklist remains the same at each visit.

9.5 Monitoring and Evaluation

9.5.1 Data Collection and feedback system

Feedback for supervision assessment (OTSS) of laboratory

The basic elements of the system used to monitor and evaluate the quality and progress of OTSS should be both qualitative and quantitative and include:

- the national supervisory oversight mechanism (qualitative);
- the feedback mechanism between OTSS supervisors and coordinators (qualitative); Annex – 11
- the technical competence of OTSS supervisors (quantitative); and
- analysis, interpretation and dissemination of OTSS data (quantitative and qualitative) between supervising teams, health management teams and health facilities.

9.5.2 Reporting

OTSS produces not only data to be reported to national health information systems but also data for indicators of malaria case management.

Progress and output indicators

- the number and percentage of OTSS supervisors who have been (re)trained in malaria microscopy, use of RDTs, clinical case management of febrile illnesses or OTSS practice and methods;
- the number and percentage of OTSS visits;
- the number of mentoring activities conducted and clearly linked to identifiable performance issues;
- the number of on-site training activities conducted and linked to identifiable performance issues;
- the number and percentage of bench aids provided as a result of OTSS visits; and
- the number and percentage of SOPs provided as a result of OTSS visits.

9.5.3 Measuring the impact of OTSS

The effectiveness of OTSS depends on a number of proposed outcome indicators:

- supervisor performance in malaria microscopy and RDTs;
- supervisor competence in identifying and rectifying errors in performing microscopy or RDTs;
- supervisor knowledge of clinical case management of febrile illness;
- health worker performance in conducting malaria microscopy and RDTs, including in
- facilities that meet quality standards (composite indicator);
- health worker adherence to national guidelines for diagnosis and treatment of malaria,
- with appropriate:
    - clinical consultation practice,

    - diagnostic measures,
    - diagnosis,
    - use of test results,
    - treatment practices and
    - patient counselling;
- routine, appropriate internal QA measures;
- stock-outs of essential malaria microscopy supplies, RDTs and essential drugs (including antimalarial drugs); and
- readiness of a facility to diagnose and treat patients with fever or malaria (composite indicator).

OTSS visits are dynamic; supervisors must exercise judgement in negotiating with the management and staff of the health facility about which deficiencies should be addressed before the next supervisory visit. Although, supportive supervision is costlier than training alone, it can better increase worker performance.

Figure 4 – Flow diagram for QAQC performance, supervision and monitoring (OTSS) with standard sets of slides (source: Guideline for Quality Assurance and Quality Control of Malaria Microscopy in Myanmar, October 2014)

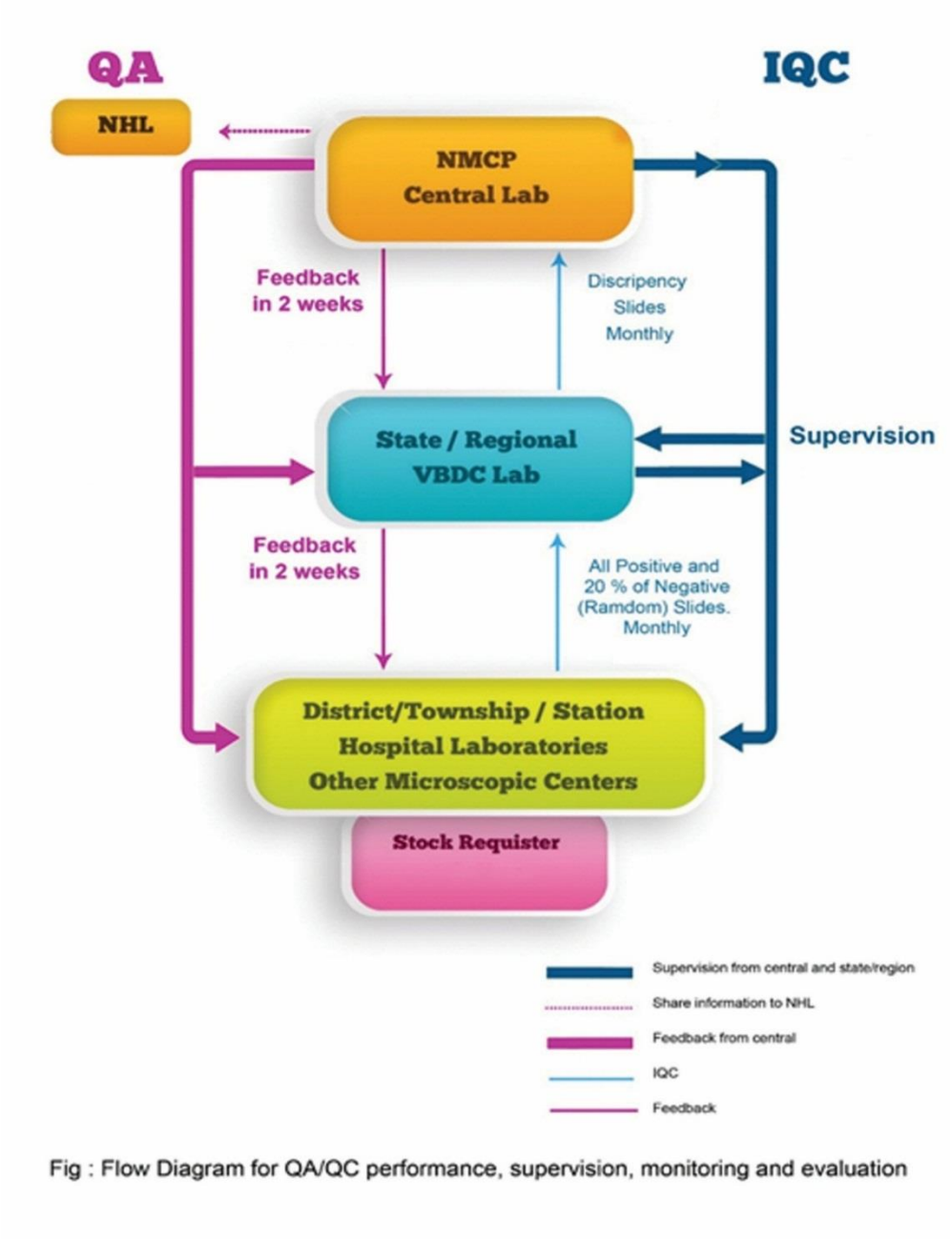


Fig : Flow Diagram for QA/QC performance, supervision, monitoring and evaluation

A simple random selection of lot number of RDT from end users will be conducted twice yearly and send that sample to DMR or NMCP laboratory for quality assurance. The result will be shared to township, State/Region, Central VBDC, suppliers and partners for quality assurance.

10. SETTING UP A SLIDE BANK

Provision and maintenance of a set of high quality and well characterized malaria reference slides is essential part of all national QA programme to support the training of microscopists and accreditation of their expertise.

Model Minimum Slide Sets for Accreditation of Trained Laboratory Staff in Malaria Microscopy at Malaria Reference Laboratory (include State/Region Laboratories).

Slide set 1 (40 slides): Assessment of presence/absence of parasites, and species identification

- 20 negative slides:– 20 'clean' negatives
- 20 positive slides of low density (80-200 parasites/microliter):
- Time limit: 10 minutes per slide

Slide set 2 (15 positive slides): Assessment of quantitation

- Time limit: 10 minutes per slide

Standard sets of blood slides for accreditation/ training should depend on the local prevalence of malaria species (*i.e.* number of *Pf*/ F+g/ Fg/ *Pv* slides/ *Pm*/ *Po*)

10.1 The need

A well characterized and high quality malaria reference slide sets needed for the continuous training and assessment of skill level of laboratory technicians who will become managers and supervisors under the national QA programme. NMCP should develop its own malaria slide banks to support its QA programme.

10.2 The composition of a slide bank

- Malaria slide banks should contain, as a minimum, slides of all malaria species currently found in the country and malaria parasite, as well as negative slides.
  - If feasible, local zoonotic species commonly found in the country should be included such as P. *knowlesi* and microfilaria species.
- The number of slides and relative proportion of each category should be based on the parasite prevalence and average density across the spectrums of malaria transmission encountered by the national programme.
- The size of the slide bank should be assessed, taking into consideration the following minimal parameters:
  - Number of laboratories and technicians;
  - Number of training courses and assessment rounds to be held each year;
  - the state of development and characteristics of the QA system;
  - Implementing partner organizations or agencies that may be granted access to the slide banks to be in-line with the national QA/QC standard; and available resources
- A policy on access to the bank will need to be developed along with user guide.
- All slides in malaria slide banks should be validated by 3 independent Expert Level microscopists from reputable laboratories. When possible, it is recommended that the

samples to be used for slide bank preparation should be confirmed by polymerase chain reactions (PCR) techniques.

References:

1. Malaria microscopy Quality Assurance Manual, version 2, WHO
2. Guidelines for Quality Assurance and Quality Control of Malaria Microscopy in Myanmar 2015 by CAP-Malaria with technical support of NMCP

Annex-1 MALARIA MICROSCOPY REGISTRATION FORM FOR ROTUINE REGISTER & CROSSCHECKING (RDT)

MALARIA MICROSCOPY REGISTRATION FORM

..... State/Region ..... Hospital / VBDC ..... Station Hospital ..... RHC Month..... Year.....

Date	Sr No;	Blood Slides No;	Patient's Name	Age	Sex		Address (Ward)	Source of infection	Registration Number		Microscopy Result								RDT Result				Remark
					Male	Female			OP	IP	Neg	Pf	Pf+g	Pf	fg	Count	Pv	Pm/Po	Mix	Pf	Pv	Mix	Neg

QUALITY CONTROL ,Cross Checking slides				
Blood Slides No;	Remark		Query	Remark
	+/-	Agreement (+/-) Finding (Pf/Pv/Pm /Po/Mix/ NMPS)		

***On a monthly basis, all Malaria positive slides and 20% of randomly selected negative slides should be sent from each laboratory center to the State/Regional VBDC laboratory for IQC.**

*** If total slides examined at a particular laboratory are less than (50) in numbers, all slides must be sent for IQC.**

Signature .....

Name of Validator .....

Date .....

Annex-2 REAGENTS AND EQUIPMENT LIST OF MALARIA MICROSCOPY

ITEM	QUANTITY	TYPICAL PACKAGING	COMMENTS
GLOVES, examination, latex, disposable, medium	15 boxes	50 pairs/box	Approx. 1 year supply/person
LENS CLEANING SOLUTION, 1 L, bottle of Xylenes 100 cc	1 L	1 litre bottle	
LAB MARKER, black, dye/bleach/wash resistant	6	Roll	
COTTON WOOL, hydrophilic, ROLL, 500g	1 Roll	500 cotton swabs	Approx. 1 year supply
LANCET, disposable, sterile, standard type	10 boxes	200 lancets/pack	Approx. 1 year supply
SHARPS CONTAINER, needles	10	individual packaging	Approx. 1 year supply
NEEDLE, sterile, 21G	1 box	100 needles/pack	Approx. 1 year supply
SLIDE, 76x26mm, 1.0mm-1.2mm thickness	60 boxes	72 slides/box	
LENS CLEANING PAPER, sheet	1	100 sheets/booklet	
PIPETTE, TRANSFER (Pasteur), graduated, plastic, non-sterile	500 pipettes		
CHLORINE, 1g (NaDCC/ dichloroisocyan. Sodium 1.67g tablets or bleaching powder	100 tablets	100 tablets	1 tablet provides 0.2L of a 0.5% chlorine solution. 100 tablets = 10 L of a 1 % solution/L
PENCIL, grease, red glass writing	2		
FUNNEL, plastic, 90mm diameter, short end	2		
RACK, FOR SLIDES, expendable, stainless steel	1		
TIMER, Digital 60mn with alarm	3		
RACK FOR DRYING SLIDES, vertical, plastic 10 slides	3		
CYLINDER, MEASURING, plastic, graduated, spout, 250ml	1		
BOTTLE, glass, brown, screw cap, 1 L	3		
TALLY COUNTER 4 digits hand operated	2		
MICROSCOPE LIGHT	1		

ITEM	QUANTITY	TYPICAL PACKAGING	COMMENTS
BATTERY-POWERED , MICROSCOPE LIGHT (e.g. with white LED light)	1		If no reliable external power source
SLIDE BOX, for 100 slides	12		
BEAKER, graduated, glass 100ml	1		
STAINING JAR, glass, with lid	2		
ROD, glass, 250 mm diameter 6mm-7mm	2		
MICROSCOPE, binocular with electric light source, x 10 (and x7) eyepieces and oil immersion lens	1		
OIL, IMMERSION, 500ml, bottle (Anisol)	1	Enough for approx. 10,000 slides when using 50 µL of oil (drop)	
METHANOL, 1L, bottle	4	Approx. 2000 slides can be fixed with 1 L methanol	
GIEMSA STAIN 500ml bottles	5	1600 slides/ 500ml	
Manuals	1		
NMCP SOPs for malaria microscopy	1		
Bench aids for the diagnosis of malaria infections: 12 color plates: WHO, 2008. - 3rd Edition			

Annex –3 STOCK BOOK (Sample)

No	Date	Brand Name	Expired Date	Quantity			Received from	Sent to
				In	Out	Balance		

Annex – 4 STOCK REQUEST FORM (Sample)

No	Date	Item	Quantity	Remaining Balance	Remark

Annex – 5 STOCK SUPPLY FORM (Sample)

No	Date	Item	Brand	Expired Date	Quantity

Annex – 6 FORMAT USED FOR DISPATCH OF SLIDES FOR CROSS CHECKING AND FEEDBACK

Date of Slide sending..... Date of returning validated results.....
State/Region ……Township ……
Health center/Hospital laboratory /VBDC .....
Name of Technician (who sent the slides)……Designation……

Sr	List of blood smears sent from the lab mentioned above			Results returned after Cross-checking by the higher level		
	Slides No.	Parasite Species	No. of asexual stages Count	Correct Species	Correct Count	Remark A, B, C, D
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
A	**True positive** (slides reported as positive by both readers)					
B	**False positive** (slides reported as positive in routine testing but negative by cross checker)					
C	**False negative** (slides reported as negative in routine testing but positive by cross checker)					
D	**True negative** (slides reported as negative by both readers)					

According to the formula given in SOP-7, the followings must be calculated and mentioned.

(1) % of Agreement – .....% (4) False Positive - .....

(2) Sensitivity – .....% (5) False Negative - .....

(3) Specificity –..... %

Suggestions for Action to be taken by the lab (dispatched) -

.....
.....
.....
.....
.....

Signature of dispatcher..... Signature of Validator……
Name of dispatcher ..... Name ……
Designation ..... Designation ……
Date ..... Date ……

Annex – 7 REQUEST AND REPORT FORM FOR PENAL TESTING

THE REPUBLIC OF THE UNION OF MYANMAR
MINISTRY OF HEALTH AND SPORTS
DEPARTMENT OF MEDICAL SERVICES
NATIONAL HEALTH LABORATORY
35, HMAW KUN DAIK STREET, YANGON

Ref: .....
Date: .....

Microbiology Quality Control Form
Distribution No (111)

Job No …….

Request & Report Form for Specimen No

Type of Specimen (1) Blood Film (stained)

(2) Blood Film (unstained)

(3) Stool RE

(Please return the slides & slide-box to NHL)

REPORT

Specimen (1) Blood Film (stained)

Specimen (2) Blood Film (unstained)

Specimen (3) Stool RE

Results performed by

Name of Technician ……..
Laboratory ……
Hospital …….

Supervised by

Personnel-in-charge ……..
Laboratory ……
Hospital ……

Annex – 8 RESULTS FOR THE EQAS

THE REPUBLIC OF THE UNION OF MYANMAR
MINISTRY OF HEALTH AND SPORTS
DEPARTMENT OF MEDICAL SERVICES
NATIONAL HEALTH LABORATORY
35, HMAW KUN DAIK STREET, YANGON

Ref: .....
Date .....

Results for the EQAS (Microbiology)
Distribution No (111)

Job No ( )

Parasitology Section
Date of Distribution:

Expected Results: (Sample)

Specimen (1) Malaria parasites present. *Plasmodium vivax* (+) seen.

Specimen (2) Malaria parasites present. *Plasmodium vivax* (+++) seen.

Specimen (3) Cysts of *Entamoeba histolytica* and
Ova of *Trichuris trichiura* seen.

Scoring for your Results:

Specimen (1): .....

Specimen (2): .....

Specimen (3): .....

Maximum score: **Grade 4**

Your average score: .....

National Health Laboratory

Annex – 9 CHECKLIST FOR SUPERVISION (OTSS) OF MALARIA MICROSCOPY LABORATORY STATUS

Region/ State ……Township…… Date:……

General Hospital/Station Hospital/RHC ……..

Name of staff……Designation……

Name of Technicians	Years of experience	Training			
		Frequency	Days.	Last date	Topic

Slides examined/day – ( ) No. Slides examined/year – ( )

Y = 1, N = 0

GENERAL CONDITION OF LABORATORY

	Checklist Question	Y/N	Remark
1	Is the room or work place kept neat and tidy?		
2	Are the equipment, chemical and utensil kept properly?		
3	Is the room well ventilated with enough light?		
4	Electricity		
5	Water supply		
6	Waste management system - properly set up?		
	Total		

CHEMICALS FOR STAINING

	Checklist Question	Y/N	Remark
1	Is the staining solution (working solution) used within one hour?		
2	Are the solution and chemical bottles kept in cool, dry place and away from sunlight?		
3	Are the staining solution and chemicals enough in stock?		
4	Is the stock Giemsa stain bottle properly closed when it is not in use (Screw tight)?		
5	Do you use (10%) Giemsa staining solution?		
6	Is working solution prepared properly?		
	Total		

MICROSCOPIC SLIDES

	Checklist Question	Y/N	Remark
1	Are the glass slides cleaned before use?		
2	Are the glass slides well packed and kept properly before use?		
3	Are the steps performed in taking blood of patients correct?		
4	Are the steps performed in making blood films on the slides correct?		
	Total		

SAMPLE PREPARATION AND EXAMINATION

	Checklist Question	Y/N	Remark
1	Do you prepare both thick and thin smears from one patient?		
2	Do you prepare both thick and thin smears on one glass slide?		
3	Do you observe (200) fields in thick smear before giving the result?		
4	Do you report result from one patient within (45) minutes?		
5	Do you report the MP result in species?		
6	Do you report MP result in parasite's stage?		
7	Do you report the parasites count in the result?		
8	Do you send slides to Region/State VBDC or Central VBDC (or any other facilities) for CROSS-CHECKING?		
	Total		

RDT

	Checklist Question	Y/N	Remark
1	Do you examine RDT along with Microscopic examination?		
2	If YES, who request for RDT examination? (Medical Doctor-1, Nurse-2, Lab tech-3, Microscopist –4,Patient -5, Other -6)(Tick according to the answer)	1 2 3 4 5 6	
3	Brand of RDT		

STORAGE AND MAINTENANCE OF EQUIPMENT AND REAGENTS

	Checklist Question	Y/N	Remark
1	What do you use to wipe out immersion oil on objective lens? (Cloth-1; No need to wipe because we use Anisole-2; Others -3)	1 2 3	

2	Do you cover the microscope with Plastic Dust Cover when the lab is closed (especially at night, weekend, national holidays)		
3	Do you put the microscope back in the box or cabinet when the lab is closed (especially at night, weekend, national holidays)		
4	Do you use special method /items to avoid mold?		
5	Do you have special container, box or shelf to store glassware?		
6	Do you have special container, box or shelf to store reagents?		
7	Who manages the Key of the lab?		
	Total		

SUPPLY SYSTEM

	Checklist Question	Y/N	Remark
1	Do you have a file for stock in and out?		
2	Do you have stock request form/ indent form?		
	Total		

ITEMS	Source & Frequency of SUPPLIES					
	VBDC	CMSD	NHL	OTHERS	HOW OFTEN	**Remark**
Lancets						
Glass Slides						
Giemsa stain						
Immersion Oil						
Methanol						
RDT						

REPORTING SYSTEM

	Checklist Question	Y/N	Remark
1	Do you use malaria microscopy? How many blood smears did you examine in last year?		……. slides
2	Do you have a format of **reporting form** to fill the result (on Malaria Microscopy)?		
3	Do you report malaria microscopy data? **Where and when do you report** your routine malaria slides examination?		……. …….
4	Do you report parasite species with staging and parasite count?		
	Total		

General findings and recommendations

Supervisor / Validator's comments:

Annex – 10 ACCURACY OF MICROSCOPIC EXAMINATION OF BLOOD SLIDES
(Checking with Standard Slide Set during Supervision (OTSS) Visit)

Region/State ……Township …… Date……..……
VBDC/General Hospital/Township Hospital/ Station Hospital/RHC ……..……
……..……
Name of staff…… Designation……

Sr	Slides Number	Parasite Species	No. of asexual stages Count	Correct Species	Correct Count	Scoring	Remark
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

MICROSCOPE

Sr	Microscope Brand	Model	Bi/Monocular	Light/Electric	Function +/-
1					
2					
3					
4					

PARTS OF MICROSCOPE

Parts EXD:	Microscope Brand/Model	Any defect identified	Repaired during visit
Eye Pieces			
Objectives			
Condenser			
Mirror			
Light Source			

Signature of Supervisor……..
Name.....
Designation ……

Annex – 11 FEEDBACK FOR SUPERVISION ASSESSMENT (OTSS) OF LABORATORY

(For Feedback to the TMO or concerned authority immediately after supervision)

Region/State ……Township ……Date of Supervision…….

Place of supervision - VBDC/ General Hospital/Township Hospital/ Station Hospital/RHC

.....

Name of laboratory incharge ……Designation……

CHECKLIST	MAX SCORE	RESULT SCORE	REMARKS
GENERAL CONDITION OF LABORATORY	**6**		
CHEMICALS FOR STAINING	**6**		
MICROSCOPIC SLIDES	**4**		
SAMPLE PREPARATION AND EXAMINATION	**8**		
MICROSCOPE FUNCTIONING	**1**		
STORAGE AND MAINTENANCE OF EQUIPMENT AND REAGENTS	**5**		
SUPPLY SYSTEM	**2**		
REPORTING	**4**		
TOTAL	**36**	A	

Score on observation of laboratory = ……A……

% of scoring result of laboratory = ……A…/36 = …….

No	Name	Designation	No. of Slide	True (+) ve	False (+) ve	False (-)ve	True (-)ve	Malaria knowledge (Theory)	% of Agreement result

Result of Proficiency testing = …….

(% of agreement result formula= TP+TN/Total slides)

General findings and recommendations

Signature of Supervisor……..

Name of Supervisor……

Designation.....

Annex – 12 SUPERVISORY CHECKLIST FOR RDT QUALITY ASSURANCE

Date of Visit: |__ __| |__ __| |__ __|
dd/ mm/ yy

State: _____

Township: _____

Health Station: _____

Monitored by: _____

QA Officer: _____

Time Start: |___||___|: |___||___| am / pm

Time End: |___||___|: |___||___| am / pm

(Tick all boxes of the choices applicable.)

Type of RDT Storage Area: ☐Rural Health Center ☐Township
☐Village Health Workers ☐Others *(Specify.)*_____

Type of RDT Testing Area: ☐Rural Health Clinic ☐Mobile(house-to-house)
☐Barangay Health Center ☐Others *(Specify.)*_____☐Own Residence

Name of RDT Service Provider / BHW / Respondent:_____

Date of last training/refresher course on RDTs, if any: |__ __| |__ __| |__ __|
dd/ mm/ yy

Conducted by: _____

How long has the HW been conducting rapid diagnostic testing? |__ __| years *and/or* |__ __| months

General Directions. For some questions, check (☑) the corresponding box of the appropriate answer. It is recommended that further comments and remarks be provided on the space allotted. Also, some questions may need a specific and written answer.

I. RAPID DIAGNOSTIC TESTS

RDT stocks inventory – based on last supply

Date of Last Supply (dd/mm/yyyy): |___|/ |___|/|_____|

Brand of RDT:

_____

Lot Number: _____ Expiration Date (mm/yyyy):

|_____|/|_____|

Quantity Received: |____| boxes x |____| |____| tests = |____| |____| total number of tests

Remaining stock: |____| |____| tests Adequate before the next requisition? ☐Yes☐ No

Transport and Storage of RDTs	
Transport condition of RDTs *(Tick all boxes that apply.)*	☐Transported in an air-conditioned vehicle? ☐Not directly exposed under the sun? ☐Others? _____
Storage condition of RDTs *(Tick all boxes that apply.)*	☐Stored in a cool and shaded area ☐Others? _____

II. TESTING SET-UP AND SUPPLIES

	Y	N	Comments / Remarks
A. Testing area/conditions			
1. Bench space (or table and chair/bench for patient)?	☐	☐	
2. Adequate lighting (not necessarily electric lighting)?	☐	☐	
B. Supplies and Drugs– Presence of the followings:			
3. Rubbing alcohol / 70% isopropyl alcohol? / Alcohol swabs?	☐	☐	
4. Blood lancet?	☐	☐	
5. Puncture-proof container?	☐	☐	
6. Cotton / cotton balls?	☐	☐	
7. Timer?	☐	☐	
8. Functional weighing scale?	☐	☐	
9. Others? (Body thermometer? Gloves? Etc.?)			
10. What are the antimalarial drugs available in the facility?	☐Coartem © ☐Paracetamol/antipyretic ☐ Others: ☐Primaquine ☐Chloroquine _____		
11. Have you experienced stock-outs of supplies and drugs in the past three to six (3-6) months?	☐	☐	☐Supplies: _____ _____ ☐Drugs: _____ _____ When? _____
12. Duplicate copies of Facility Inventory Reports available in the RDT site?	☐	☐	
13. In the Facility Inventory Report, information on expiration dates, lot numbers and batch numbers, recorded completely and legibly?	☐	☐	

III. RAPID DIAGNOSTIC TESTING PROCEDURE*

***Done on a prospective patient for the day; otherwise, steps shall be narrated to the monitor

	Done	Not Done	Comments / Remarks
A. Pre-RDT Procedure			
1. Register patient in the malaria registry book (complete all needed patient information)?	☐	☐	
2. Prepare/gather all materials needed on the working table?	☐	☐	
3. Take body temperature?	☐	☐	
B. RDT Proper			
4. Procedure explained to the patient or caretaker?	☐	☐	
5. Expiration date checked?	☐	☐	
6. Silica gel / desiccant checked?	☐	☐	
7. Device labeled with RDT number, patient's name, age and date of test?	☐	☐	
8. Gloves worn for both hands?	☐	☐	
9. Finger disinfected and allowed to dry before pricking?	☐	☐	
10. Right amount of blood collected in the blood collecting device?	☐	☐	
11. All collected blood deposited in right hole?	☐	☐	
12. Correct number of drops of buffer delivered to the right hole?	☐	☐	
13. Proper timing observed before reading test result?	☐	☐	
14. Tentative marks of (+) and (-) written on the test cassette?	☐	☐	
15. Proper interpretation of test result?	☐	☐	
16. Lancet, blood collecting device gloves and alcohol swab disposed of in respective containers?	☐	☐	
17. Used test cassette kept for monitoring purposes?	☐	☐	
18. Result recorded accurately in the registry?	☐	☐	
C. Post-RDT Procedure			
19. Weigh patient, if positive?	☐	☐	
20. Instructions given on how the medication should be taken?	☐	☐	

21. Drugs dispensed?	☐	☐	
22. First dose of drug given in the facility? (supervised treatment)	☐	☐	
D. Rating of RDT Cassettes *(per criterion)* *****			
23. Clearly written RDT number (from the patient register), name or patient ID from the registry, sex, age of patient and date on the cassette?	|___|/|___| =|_____|%		
24. No stray drop/s of blood outside the sample well?	|___|/|___| =|_____|%		
25. Tentative marks of (+) and (-) written for ease of interpretation?	|___|/|___| =|_____|%		
26. Repeat-testing was done for RDTs that tested invalid? (Show RDTs.)	☐	☐	
E. Ratings of RDT Cassettes *(combination of all criteria)* *			
27. Passed all indicated criteria under 23 – 25?	|___|/|___| =|_____|%		

***** Percentage of test cassettes adhering to the mentioned criteria. (≥ 80%: PASS; < 80%: FAIL)

IV. BIOSAFETY AND WASTE DISPOSAL

	Y	N	Comments / Remarks
1. Waste container for dry wastes/trash?	☐	☐	
2. Waste container for infectious wastes available?	☐	☐	
3. Puncture-proof sharps containers available?	☐	☐	
4. Type of final waste disposal used?	☐Cemented septic vault ☐Burying or deep pit ☐Others(Specify: _____)		
5. Are gloves worn during the final disposal of wastes?	☐	☐	

V. DOCUMENTATION

	Y	N	Comments / Remarks
1. Malaria Patient Registry book available in the facility?	☐	☐	
2. In the Malaria Patient Registry book, the following information are recorded completely and legibly: date of examination and	☐	☐	

collection, name, age, sex, address, examination result, history of travel and number of anti-malarial drugs given?			
3. Summary or total number of positives, negatives and drugs given, recorded completely and legibly?	☐	☐	
4. Blank Malaria Patient Registry forms available?	☐	☐	
5. Duplicate copies of accomplished Malaria Patient Registry forms available in the facility?	☐	☐	
6. Blank Malaria Monthly Report forms (including PhilMIS forms) available?	☐	☐	
7. Completes and submits malaria monthly report form (including PhilMIS form)?	☐	☐	
8. Blank Stock Withdrawal forms available?	☐	☐	
9. Completes and submits Stock Withdrawal form?	☐	☐	
10. Job aid / training manual available (including treatment guidelines)?	☐	☐	

VI. SUMMARY OF COMMENTS AND RECOMMENDATIONS

Particulars	Summary of Comments	Recommendations
Rapid Diagnostic Tests		
Testing Set-up and Supplies		
Rapid Diagnostic Testing Procedure		
Biosafety and Waste Disposal		
Documentation		

FOLLOW-UP VISIT*

Date of Visit: |__ __| |__ __| |__ __|
dd/ mm/ yy

Monitored by: _____

QA Supervisor: _____

Points for Improvement	Recommended Corrective Actions	Improvements Noted

* For RDT sites which did not pass the 80% cut-off

UNIVERSITY RESEARCH CO., LLC