

National Malaria Laboratory Plan 2020-2025



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FOREWORDS

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ABBREVIATIONS

ACD: Active Case Detection

CHUs: Community Health Units

D/MCs: Designated Microscopic Centers

DoHS: Department of Health Services

DHO: District Health Office

ECAMM: External Competency Assessment for Malaria Microscopists

EDCD: Epidemiology and Disease Control Division

EQA: External Quality Assessment

GLP: Good Laboratory Practices

GMP: Good Manufacturing Processes

HPs: Health Posts

NCAMM: National Competency Assessment for Malaria Microscopists

NPHL: National Public Health Laboratory

PACD: Proactive case detection

PCD: Passive Case Detection

PCR: Polymerase Chain reaction

PHCCs: Primary Health Care Centers

PPHL: Province Public Health Laboratory

PT: Proficiency Testing

QA: Quality Assurance

QC: Quality Control

RDTs: Rapid Diagnostic Test Kits

RACD: Reactive case detection

SDPs: Service Delivery points

SOPs: Standard Operating Procedures

TWG: Technical Working Group

UHC: Urban Health Clinic

VBDRTC: Vector Borne Disease Research and Training Center

VDC: Village Development Committee

WHO: World Health Organization

WMR: World Malaria Report

1. INTRODUCTION

Malaria is caused by the parasites belonging to the genus *Plasmodium* and is one of the most widespread diseases all over the world. An estimated of 228 million cases of malaria was recorded around the world in 2018. Major burden of this disease is in the WHO African region accounting 85% of the total followed by the WHO South- East Asian region (3.4%) and then the WHO Eastern Mediterranean region (2.1%). The WHO South-East Asia Region continued to see its incidence rate fall – from 17 cases of the disease per 1000 population at risk in 2010 to 5 in 2017 (a 70% decrease). (WMR 2018)

Plasmodium falciparum is the most prevalent malaria parasite in the WHO African Region, accounting for 99.7% of estimated malaria cases in 2018, as well as in the WHO regions of South-East Asia (50%), the Eastern Mediterranean (71%) and the Western Pacific (65%). *P. vivax* is the predominant parasite in the WHO Region of the Americas, representing 75% of malaria cases.

In 2018, there were an estimated 405 000 deaths from malaria globally, compared with 416 000 estimated deaths in 2017, and 585 000 in 2010. Children aged under 5 years are the most vulnerable group affected by malaria. In 2017, they accounted for 67% (272 000) of all malaria deaths worldwide. In 2018, only WHO African region and the WHO south-East Asia Region showed reductions in mortality compared with 2010. The largest declines had occurred from 533000 in 2010 to 380 000 in 2018. Despite these gains, the malaria mortality reduction rate has also slowed since 2016.

Following the commitment to achieve elimination, significant progress has been made throughout the world. In the South East Asia Region, Maldives and Sri Lanka were certified as Malaria free (malaria eliminated) and Timor-Leste will follow soon.

Nepal is also showing significant potential to achieve the goal of malaria elimination by 2026. Nepal has set goals to reduce the incidence of locally transmitted malaria cases by 90% and the number of VDCs (village development committees) having indigenous malaria cases by 70% of current levels by 2018. There are no deaths recorded from malaria in Nepal since 2012 and it is strictly maintained so (WHO 2018).

According to 2019 microstratification, 15 districts in Nepal have high risk ward, 18 district have moderate risk wards and 67 districts low risk wards. An estimated total population of 12,485,584 in 2686 wards are at the risk; 0.67% of the total population lies in high-risk wards (47), followed by 3.19 % in moderate-risk wards (151); 37.9% in low-risk wards (2488) and 58.2% of population living in No risk 4057.

The National Strategic Plan (2014-2025) envisions elimination of malaria by 2025 and set following objectives to achieve this status:

- To strengthen surveillance and strategic information on malaria for effective decision making.
- To ensure effective coverage of vector control intervention in the targeted malaria risk areas.
- **To ensure universal access to quality assured diagnosis and effective treatment for malaria.**
- To develop and sustain support from leadership and communities towards malaria elimination.
- To strengthen programmatic technical and managerial capacities towards malaria elimination

In order to achieve malaria elimination status by 2026, one of the prerequisite is attainment of universal & timely access to quality assured diagnosis and effective treatment. And, identification of malaria parasite is key to providing correct treatment.

While global predominant parasite species is *Plasmodium falciparum*, in Nepal, the most common species is *Plasmodium vivax* which accounts for 93% of reported cases in 2018, whereas *Plasmodium falciparum* is seen only in 7% of the cases. Sudurpashchim province shows the highest burden of the disease while Gandaki province and Province 1 record the lowest burden.

There are multiple tests available in the market for malaria diagnosis. In an elimination setting, every single case of malaria has prime importance and it has to be detected at earliest possible with a standard and reliable diagnostic methods as per the National malaria treatment protocol 2019. Quality assurance of all the diagnostic tools at all health facilities from center to peripheral level is critical for malaria elimination certification by WHO and prevention of re-introduction of malaria in the country.

2. LABORATORY DIAGNOSIS OF MALARIA IN NEPAL

2.1 Standard tools for diagnosis of malaria

WHO recommends parasitological confirmation of malaria in all settings by quality assured diagnosis before treatment is started. A diagnosis of malaria can be confirmed rapidly by good-quality microscopy or RDT. In line with that the National Malaria Treatment Protocol (NMTP) 2019 recommends all suspected malaria cases should have a parasitological test either by quality assured microscopy or RDT to confirm the diagnosis. Quality assured microscopy should be used where available. In some specific situations (e.g. monitoring treatment failure or to determine parasite density) microscopy is preferred to RDT.

Although NMTP recommends testing of all suspected malaria cases, a significant number of suspected malaria cases are reported as “clinical malaria”. The reporting of the clinical malaria is done in the Health Information Management Systems (HMIS).

2.1.1 Microscopy

Microscopy is the gold standard technique for malaria disease diagnosis. Malaria microscopy allows the identification of different malaria-causing parasites (*P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*), their various parasite stages, including gametocytes, and the quantification of parasite density to monitor response to treatment. Microscopy is the method of choice for the investigation of malaria treatment failures. Giemsa is the classical stain used for malaria microscopy, and diagnosis requires examination of both thin and thick films from the same patient. Light microscopy is the diagnostic standard against which other diagnostic methods have traditionally been compared.

The main disadvantage of the microscopy however is that it highly depends on competency of the staff. If the technicians are not trained or less qualified, species identification and quantification may be recorded wrong. It is imperative that the quality reagents, qualified manpower and quality assurance are maintained at all levels from central to the periphery health facilities.

2.1.2 Rapid Diagnostic Test (RDT)

Malaria antigen detecting RDTs are another means of diagnosing malaria disease in health facilities or active case detection in the community. RDTs can serve as an effective tool for malaria diagnosis where there are no skilled staff or when there are no microscopic centers.

The sensitivity and specificity of RDTs can however vary between different kits. Most of the WHO-PQ RDTs shows sensitivity and specificity more than 75 % at the parasite density of 200 parasites/µl (meeting WHO evaluation criteria). Some RDTs can detect only one species (*Plasmodium falciparum*), some also detect other species of the parasite as PAN (*P. vivax*, *P. malariae* and *P. ovale*).

At times, there could be some confusion in the field about when and which diagnostic tool to be chosen for malaria diagnosis. Selection of the appropriate diagnostic test tool is a key step in the health facilities to screen/diagnose malarial fever. Annex (Table 2) below provides WHO’s recommendations for the use of appropriate diagnostic tools in given criteria at different clinical settings

2.1.3: Molecular tools such as polymerase chain reaction (PCR) tests

Although detection of parasite DNA based on the PCR are highly sensitive at low parasite densities, they are not recommended and should not be used in the routine case management of malaria. PCR is used in therapeutic drug study, operational research, and other specialized epidemiological & entomological investigations.

3. QUALITY ASSURANCE (QA) IN MALARIA LABORATORY DIAGNOSIS

Quality Assurance (QA) is critical component of malaria diagnosis. QA is a broad wide-ranging concept covering all components that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the objective to ensure that the product is of the required quality for its intended use. It denotes a system for continuously improving reliability, efficiency and utilization of products and services. The activities encompass all those factors in any health care organization that are concerned with inputs, processes and outcomes of the health care system. They must not only involve every department and every health care worker but should also be integrated into the routine work of any health care organization or service, both in public and private sectors.

QA in short, refers to the sum of all activities that are performed to ensure quality of a product or service by opting and implementing Good Laboratory Practices (GLP) and Good Manufacturing Processes (GMP).

Quality Control: All the components and procedures designed to ensure that the test results (microscopy and/or RDTs) are accurate and validated

Quality Assurance: All the processes including QC that ensure there is complete confidence in the microscope results

Quality Management: Management of the laboratory to ensure QC and QA are performed in a correct and transparent manner.

WHO prequalification of RDTs is a rigorous process that involves panel testing of different density of parasites at varied temperature and humidity conditions. WHO prequalification certifies that the RDTs that have passed the tests will have the better sensitivity and specificity. Ideally, qualifying RDTs have their detection score usually more than 75% at 200 parasites/ μ l but the performance of the test kits can vary in the field conditions when the density of the parasites go below 200 parasites/ μ l.

The principle objective of malaria microscopy QA programs is to ensure that highly competent and motivated staffs dedicated to malaria microscopy are in place backed up by quality supplies of laboratory commodities and regular supervision and monitoring followed by competency assessment and other supportive malaria trainings. QA programs must be sustainable, compatible with the needs of the country and be able to fit in to the structure of existing laboratory services.

Some malaria slides from Nepal were externally assessed in 2015 and a number of issues relating to quality diagnosis was raised.

Key challenges that are observed in the field are as below

- Difficulties in maintaining microscopy facilities in good order
- Lack of adequate training and retraining of the laboratory staffs
- Lack of QA and supervision of laboratory services
- Inability to cope with the workload of the traditional systems for cross-checking of routinely taken malaria slides, often due to inadequate human and financial resources
- Poor quality of microscopy, particularly at the peripheral level
- Lack of effective supply and chain management of quality supplies
- Improper storage of reagents, slides and microscope, and also lack of maintenance of equipment
- Poor compliance with the standard guidelines for slide preparation and examination
- Choice of right test for malaria diagnosis by clinicians and the laboratory technicians is not clear.
- Poor maintenance of laboratory register

In microscopy tests, the performance of test by the health workers play the major role followed by the quality of the product and others. However, in RDTs quality assurance part, it is the RDT product selection that primarily determines the quality and performance of the RDTs. The quality for two most reliable parasitological tests for malaria requires the system which monitors all these determinants and keep in check. Figure 1 and 2 in annex below shows the limit of detection when used quality product and the relative importance of quality determinants respectively.

EDCD and NPHL with the support from Save the Children/ Global Fund, WHO and other stakeholders, and in coordination with VBDRTC and health facilities is working to improve quality of malaria diagnosis and strengthen laboratory facilities. Logistic supplies, its distribution, quality monitoring, capacity building including technical and skill development are important components of quality assurance and are on the top priority. National malaria elimination program is revising the QA/QC system according to the country's new structure with the national reference centers at the center and 7 provincial reference laboratories in the context of federalization to effectively run QA/QC in malaria diagnosis (Flow diagram 1)

4. MICROSCOPY TRAINING AND CERTIFICATION IN NEPAL

Since capacity building is critical part of quality assured malaria diagnosis, capacity building or the malaria microscopists regularly. Basic malaria microscopy training is provided to laboratory personnel who are new and are involved in malaria diagnosis throughout the country. VBDRTC

conducts 30 days of basic malaria microscopy training and 15 days of refresher training at hetauda. The refresher training is provided to the microscopists who have completed the basic malaria microscopy and have crossed at least a year or two serving in microscopy centers.

Apart from VBDRTC, microscopic training centers currently running at Kanchanpur and Surkhet are newly refurbished to conduct both basic and refresher training centers. All infrastructures and course modules and formats have been adapted and replicated as close to VBDRTC. Staff from microscopic training centers from Kanchanpur and Surkhet had attended ECAMM and NCAMM and as facilitators at VBDRTC training. New course modules and training manuals are also in process of development which will bring the uniformity in course, knowledge transfer and certification.

For certification, the participants for basic and refresher malaria microscopy are assessed based on WHO rigorous assessment standards and the microscopists are categorized as advanced and qualified based on the criteria set based on WHO standards. Those who performs extremely well are then selected for the WHO ECAMM and labeled performance based on WHO ECAMM standards. **Level one** microscopists are then used as national trainers and for QA/QC for the malaria microscopy. The grading of competency of the microscopists is shown in the annex table 3.

5. RATIONALE AND DEVELOPMENT PROCESS OF THE NATIONAL MALARIA LABORATORY PLAN

5.1 Rationale and development of the National Malaria Laboratory Plan

Since the launch of the malaria eradication programme in 1958, the burden of malaria decreased significantly in the country. As a result, the skills of the malaria microscopists decreased and due to shift in government funding priorities, the quality of malaria diagnosis was affected throughout the country. And, with the current context of federalization, it is important that a more strategic, synergistic and comprehensive malaria laboratory plan is implemented throughout the country. With the current context of federalization, it is important that a more strategic, synergistic and comprehensive malaria laboratory plan is implemented throughout the country.

This comprehensive laboratory plan (2020-2025) is intended to provide a strategic direction towards achieving a quality assured malaria diagnosis at all levels of health facilities and bring together relevant health structures such as EDCD, NPHL, VBDRTC, etc., dealing with programme implementation, malaria laboratory training, certification and quality assurance systems. The plan is also expected to address current issues and challenges related to quality assurance and ensure universal access to quality diagnosis of malaria throughout the country towards malaria free Nepal.

5.2. Process for development of the national laboratory Plan:

A workshop to develop Malaria Laboratory Plan 2020-2025 was held on 3rd Feb 2019 under the leadership of NPHL to review existing malaria diagnostic technologies and make relevant recommendations on their appropriate use to support national malaria elimination strategies; review existing QA/QC system for malaria microscopy and malaria rapid diagnostic tests (RDTs) and recommend appropriate QA/QC mechanism according to changes in country's health system and to develop National Malaria Laboratory Plan. This comprehensive laboratory plan is the outcome of this workshop and series of other consultative reviews and experts' inputs.

5.3 Target audience

The primary audience for this laboratory plan are the national program managers, laboratory managers, private health service providers, health workers involved in malaria diagnosis and quality assurance system. And, the donors and partners who support efforts of quality assured malaria diagnosis and other interventions towards elimination of malaria in the country.

6. OBJECTIVES NATIONAL MALARIA LABORATORY PLAN 2020-2025

The strategic objective of this National Malaria Laboratory Plan is to provide roadmap to ensure universal access to quality assured malaria diagnostic services in Nepal in line with National Malaria Strategic Plan, NMSP (2020-25)

The Objectives of the Malaria Laboratory Plan 2020-2025 are to:

1. Ensure functional network of quality assured laboratories in the country
2. Ensure quality assured diagnosis of malaria at all levels of health facility.
3. Establish mechanism for quality assurance/ quality control for malaria diagnostics.
4. Develop capacity of health workers in malaria diagnosis and QA/QC protocol.
5. Develop synergy of key national stake holders for implementation of this plan.

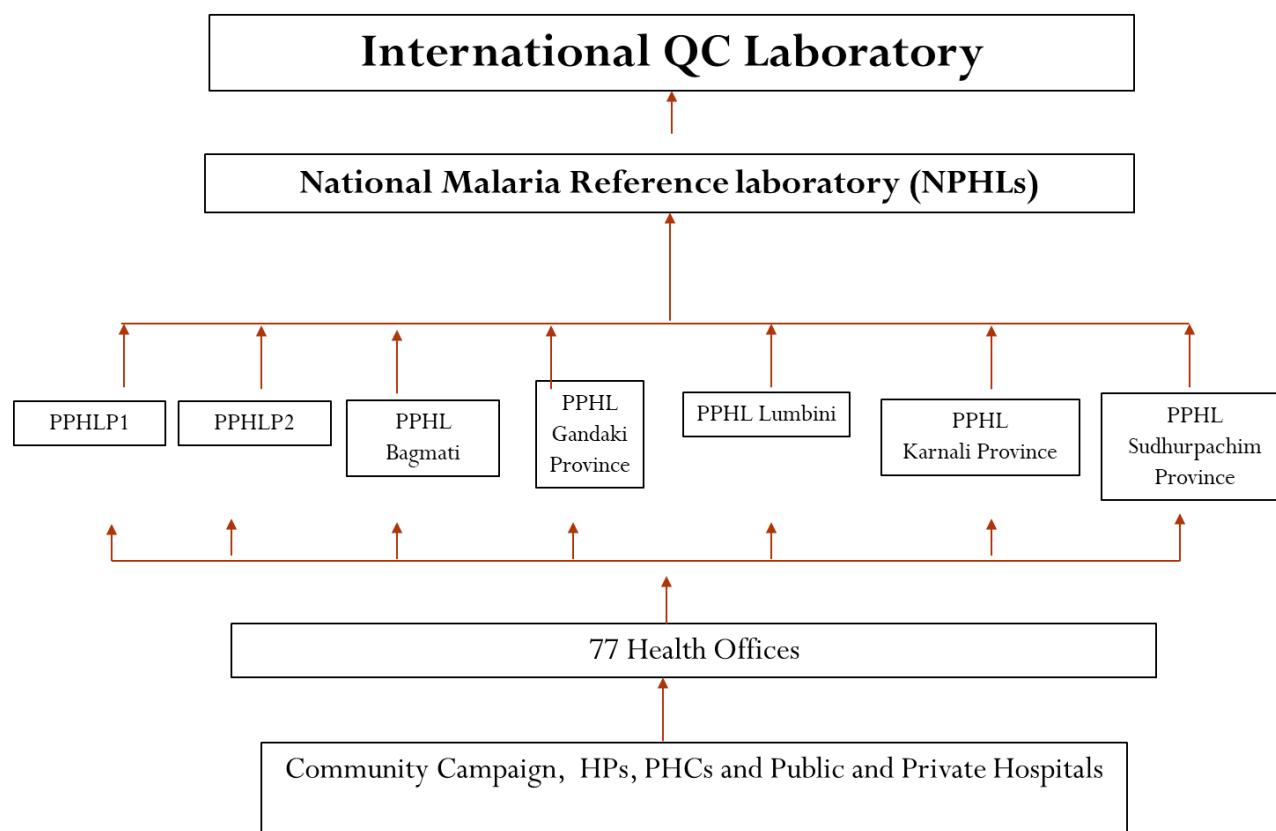
Objective 1: Ensure functional network of quality assured malaria laboratories in the country

6.1 Malaria laboratory network in Nepal:

For achieving malaria elimination, a coherent and functional network of malaria laboratories in the country with well-organized and managed structure is critical. The national malaria microscopy network will consist of three levels – national reference laboratory (NRL), provincial reference laboratories and peripheral malaria microscopy centers (public and private health facilities). There will be one national reference laboratory in the country and National Public Health Laboratory (NPHL) will serve as the national reference laboratory. Required human

resources and infrastructure will be developed at NPHL in order to serve as the national reference laboratory for quality assured Malaria diagnosis in the country.

The following is the National Malaria Laboratory Network in Nepal:



Flow diagram 1. Flow diagram of the proposed of functional laboratories in each level for cross-checking and quality control.

6.1.1 National malaria laboratory technical steering committee (NMLTSC)

At national level, malaria laboratory technical steering committee will be formed under the leadership of National Public Health Laboratory and EDCD Director. The committee will comprise of following members:

1. Director of National Public Health Laboratory
2. Director of EDCD
3. Director of VBDRTC
4. Chief of quality, Standard and Regulation Section, MoHP
5. National Malaria QA Focal Person
6. WHO
7. National Malaria Program Manager
8. PMU-EDCD
9. SCI/GF
10. Private Sector representative
11. Representatives from partners working in Malaria elimination
12. A microscopist with WHO certification level 1 from Training centers

The functions of the national malaria laboratory technical steering committee are as follows:

- 1.To coordinate at national level for malaria related laboratory policies including malaria QA, advocate for regulations and make required decisions.
- 2.To identify priority issues for quality monitoring and improvement at all levels and provide necessary support to national malaria reference laboratory (NPHL) in developing guidelines and standards.
- 3.To provide required support to national malaria program for ensuring quality of laboratory services including, equipment, commodities and supplies.
- 4.To provide technical inputs through expert groups on various issues concerning malaria laboratory services
5. To regularly review and, where necessary, propose revision of the national laboratory plan.

6.1.2 National reference laboratory (NRL) for Malaria

The National Public Health Laboratory (NPHL) will serve as the national reference laboratory for malaria. The NRL will be capacitated with adequate human resources such as a group of at least three certified (WHO accreditation level 1) malaria microscopists will be available at national reference laboratory for carrying out QA/QC activities. The principal functions of the national reference laboratory for malaria are as follows:

1. To develop the national malaria laboratory technical guidance and standards, standard operating procedures (SOPs), forms and formats for all activities related to ensuring a high quality of malaria microscopy.
2. To coordinate and guide malaria laboratory services in accordance with the plan
3. To ensure that the quality of laboratory services is maintained throughout the country through the established QA networks.
4. To make inventory of available resources including trained staffs, equipment such as microscopes, lab commodities and budget.
5. To assign a national malaria QA focal person or coordinator.
6. To collect data on current workload and assessing adequacy of resources with respect to the workload.
7. In coordination with provincial reference laboratories (i.e Provincial Public Health Laboratories), carry out an evaluation of the competency of available microscopists at all levels of the program.
8. To coordinate for deployment of trained human resources (based on need of competency level and function of health facility in diagnosis and QA/QC system).
9. To perform cross-checking of slides from provincial reference laboratories.
10. To share malaria microscopy QA/QC results with national malaria program (EDCD) quarterly and making recommendations for further improvement.
11. To provide support to national malaria program for specification, quantification and procurement of laboratory equipment, supplies and consumables.
12. To develop malaria slide bank at national level following standard operating procedures developed by WHO.
13. To develop monitoring and supervision plan and conducting monitoring visits to malaria testing sites including private sectors.
14. To provide routine malaria diagnostic services if needed.
15. To conduct malaria microscopy trainings as needed

6.1.3: Provincial reference laboratory (Provincial Public Health Laboratory)

Provincial Public Health Laboratories (PPHL) will serve as provincial reference laboratories for malaria. Under the new federal structure of the country, seven new PPHL have been approved by the Government of Nepal. Each of PPHLs will have 14 staffs with four departments including a quality control/training department. Required human resource and infrastructure will be developed at the quality control/training department of the PPHL. A group of at least two

certified (WHO accreditation level 1 or 2) malaria microscopist will be made available at provincial reference laboratory for carrying out at QA/QC activities.

The principal functions of the provincial reference laboratory for malaria are as follows:

1. To form provincial malaria QA committee and assign a provincial malaria QA focal person.
2. To establish provincial malaria QA/QC lab with a team of at least two lab personnel (WHO level 1-2) for malaria microscopy.
3. To ensure availability of guidelines, SOPs, forms and formats at service delivery points (SDPs).
4. To plan malaria activities in line with national malaria program.
5. To perform QA/QC activities such as cross-checking of slides received from district health offices and SDPs within the province.
6. To provide regular feedback to district health offices and SDPs.
7. To share results of cross-checking with NPHL on monthly basis.
8. To carry out EQA activities at the provincial level for the malaria diagnostic centers
9. To conduct basic and refresher training to public and private sectors.
10. To support in national slide banking.
11. To facilitate distribution laboratory equipment, consumables and supplies to SDPs.
12. To ensure adequate recording and reporting at SDPs.
13. To conduct periodic review meetings.
14. To conduct onsite training and supportive supervision.
15. To facilitate distribution of commodities and supplies to SDPs and to transport slides for cross-checking from SDPs to provincial reference laboratory.

6.1.4 Functions of the laboratory focal points at health office (HO)

Laboratory staff stationed at HO will receive 100% all positive and 5% of all negative slides from peripheral microscopic centers and send them to provincial reference laboratory for cross-checking. HO will also receive results of cross-checking from provincial reference laboratory and send them to peripheral microscopic centers and will facilitate implementation of reference laboratories' recommendations by microscopic centers.

6.1.5: Malaria microscopy centers

National malaria program will identify malaria microscopy centers in each province in coordination with National Public Health Laboratory, Provincial Health Directorate (PHD) and PPHLs. Designating a health facility as a malaria microscopy center will depend on the availability of a trained microscopist and level of malaria transmission risk in the area where health facility is located.

The principal functions of the malaria microscopy center are as follows:

1. To perform routine malaria microscopy
2. To collect slides from lower peripheral healthcare facilities which perform RDTs only.
3. To examine slides received and send the results back to the facilities which perform RDTs only.
4. To send 100% of all positive and randomly selected 5% of all smear negative slides to health offices in districts (or to provincial reference laboratories) for cross-checking.
5. To participate in slide banking activities when necessary
6. To maintain records of all testing, cross-checking results and feedback

All health facilities which are not a microscopy centers will have access to quality assured RDTs

Objective 2: Ensure quality assured diagnosis of malaria at all level of health facility

It is essential to establish an effective and quality assured laboratory system to provide effective malaria diagnostic services at all levels including supply of the quality assured diagnostics products, equipment and human resources. The EDCCD in collaboration with NPHL and PPHLs will designate the microscopic centers (MCs) for the country and provide malaria diagnostics throughout the country based on malaria risk stratification and ensure standards and resources available for functional MCs. The malaria diagnostics will be available till the periphery at the high risk, moderate risk and low risk wards. The RDTs for the no risk ward will stored at the selected sites where it can be accessed easily.

6.2.1 Service delivery points (SDP) for malaria diagnosis in Nepal

Local Level:

▪ Health posts (HP) and primary health care centers (PHCC):

All suspected malaria cases should be tested by RDT for diagnosis at the primary health care center (PHCC) and HP. Health posts and PHCs with quality assured malaria microscopy center and human resource (designated MC) should use microscopy to test suspected malaria. The RDT only HP/PPHC will be reporting to the MC for QA for cross-checking of malaria slides and RDT.

- **Community based Testing (CBT):**

The NMSP encourages community-based testing among high risk populations such as migrants, factory workers by mobile clinics. CBT testing is also used during the case-based investigation and as well as proactive case detection (PACD) and reactive case detection (RACD) in high risk areas, active foci during the transmission season. RDTs is used for testing of the community and reported to the health facility.

Provincial Level

- **District hospitals, tertiary, higher centers including private hospitals:**

Microscopy is the main diagnostic tool in the hospitals. A trained microscopist and a well-functioning microscope should be available at such facilities for diagnosis of malaria using microscope. However, RDTs should be made available for use outside of official laboratory operating hours and during excess workload.

- **Private health facility/private clinics:**

Malaria diagnosis and treatment are available in the private health sector. These private sectors may range from small clinics/lab, nursing home and hospitals. The diagnostic quality of these private providers will be ensured through regulatory frameworks and other approaches.

6.2.2 Interrupted supply of quality assured supplies for malaria diagnosis

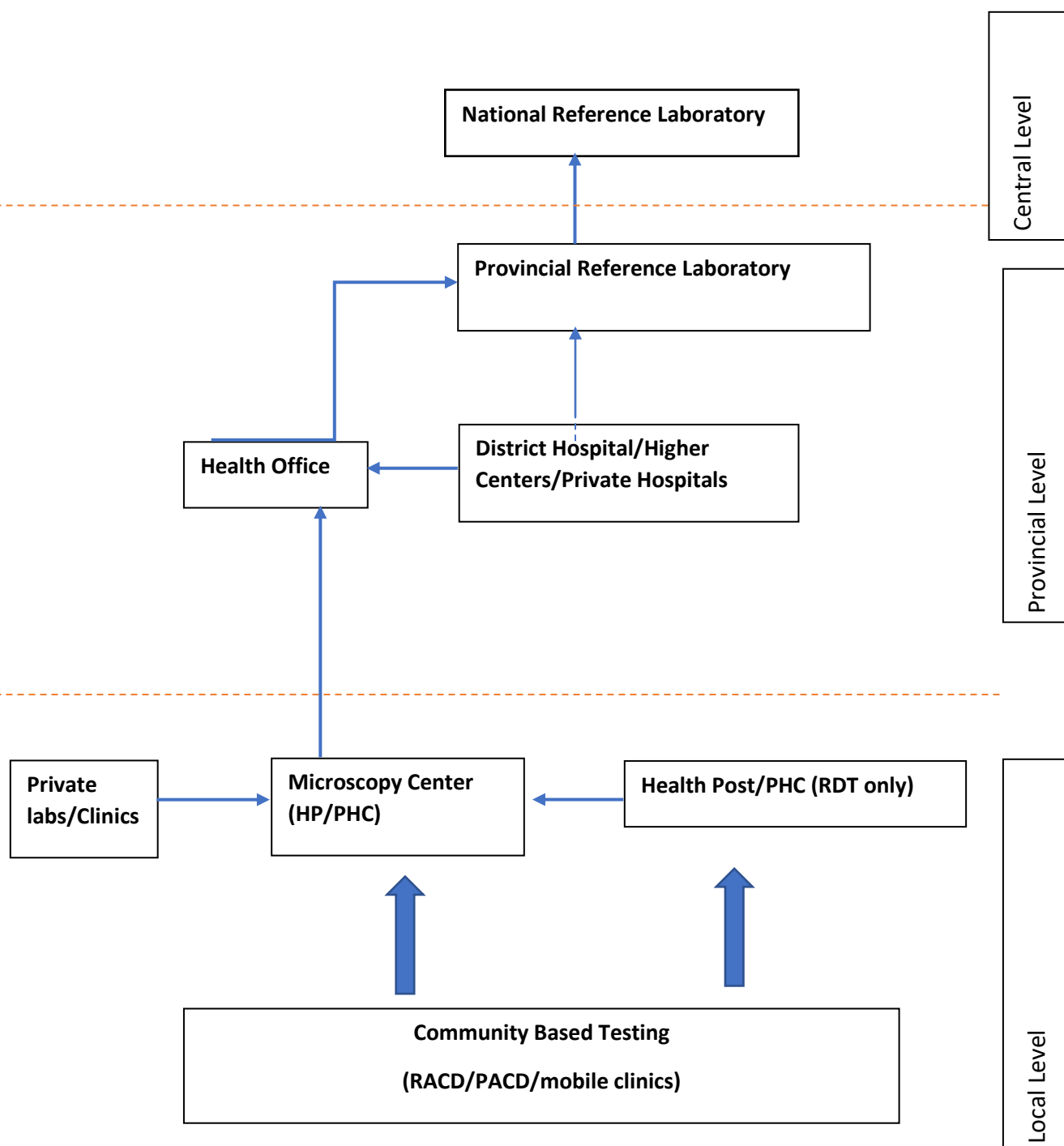
EDCD will develop a list of first line and second line WHO PQ RDTs, standards for reagents and supplies to be used by the national program. EDCD will procure malaria diagnostics centrally and will ensure uninterrupted distribution of malaria diagnostics to all health facilities and guide the provincial and local level for local level procurement. EDCD will also advocate for regulation of use of WHO-PQ RDTs in the private sectors. EDCD will hold meetings with the NRL, PRL, PHD, MoSD and local level to ensure that the malaria diagnostics and adequate human resources are available at the health facilities.

Objective 3: Establish mechanism for Quality Assurance/ Quality Control for malaria diagnostics

6.3.1 Quality assured malaria microscopy

The QA systems for diagnosis of malaria by microscopy comprise of all the processes necessary to ensure that the result is as accurate as microscopy allows, from blood collection to delivery of the results. Strengthening QA is critical component of malaria diagnosis, particularly with the reduction in the prevalence of malaria as a result of effective interventions.

The service delivery points (SDPs) points for malaria diagnosis as shown in the diagram below will participate in the national QA/QC program for malaria microscopy. It will be guided by the national QA/QC protocol and SOPs and management and operation will be guided by reference laboratory at the national and provincial levels.



Flow diagram 2: Flow of slides for cross-checking for quality assurance activities

The standardized QA/QC protocol, SOP and operational plans will be developed by the National reference laboratory in collaboration with the malaria program and implemented throughout the country. NRL will also conduct capacity building on QA/QC for the health facilities as well as the provincial reference laboratories. ECAMM will also be conducted as per needs by the NRL with support from WHO and database of level 1(L1) and Level 2(L2) microscopist will be maintained at the central level.

Reference laboratory at each level (national and provincial) should have adequate human resources including at least two certified (WHO accreditation level 1) malaria microscopists for QA/QC unit for quality assured malaria diagnosis.

6.3.2 Quality assurance of RDTs

The malaria programme and NRL will participate in WHO RDT lot testing program while procuring and conducting lot testing of RDTs from health facilities, in a WHO prequalified or ISO certified laboratory. In addition, positive control samples (such as positive control wells) will be distributed to health facilities for testing of RDTs at health facility levels. Reports of such testing will be collected and analyzed by provincial and national reference laboratories and actions will be taken where necessary.

The EDCCD will ensure lot testing of RDTs while procurement, will supply commodities required for RDTs testing at the field level and conduct testing of RDTs at the health facility level at regular intervals.

6.4. Develop capacity of health workers in malaria diagnosis and QA/QC and promote research.

6.4.1 Training and Certification

VBDRTC/NPHL will conduct basic/ refresher training on malaria microscopy at regular interval. These two centers will integrate the QA/QC orientation as part of malaria training and identify and strengthen other centers/provincial reference lab which can conduct decentralized malaria microscopy trainings. Also, a pool of national trainers for conducting malaria training will be developed and slide bank for training purposes will be maintained at the central NRL to ensure availability of standard slides for training on malaria microscopy.

Province level training centers will be mainly responsible for malaria microscopy and basic and refresher trainings in coordination with NPHL and EDCCD. Existing training centers at VBDRTC and in Surkhet and Kanchanpur will also be utilized in conducting trainings. VBDRTC and NPHL will jointly provide certifications with grading to the training participants based on the certifications criteria recommended by WHO (Table 3).

The refresher training will be provided to the microscopists who have completed the basic malaria microscopy and have crossed at least a year or two serving in microscopy centers.

Priorities for refresher training will be given to the microscopists with poorer performance and/or in que for long time post-basic malaria microscopy training. The record of all trainings and level of their competence will be stored in central data base at EDCD and or NPHL.

6.4.2 Promote researches:

In elimination settings, operational researches play an important role in generating evidence-based information that will aid in national malaria elimination efforts. Any research efforts must be encouraged, and laboratories must be involved where necessary for research efforts geared towards malaria elimination in the country. Research must be prioritized based on needs and not limited to some examples such as G6PD deficiency in Nepalese population, therapeutic efficacy studies (TES), entomological studies, etc. Capacity for appropriate programmatic researches will also be built based on needs.

6.5. To develop synergy of key national stake holders for implementation of this plan.

EDCD will hold regular meeting of key national stakeholders, partners for implementation of this laboratory plan. Each stakeholder particularly laboratories at various levels will ensure adequate human resources and a focal unit/person at each institution to implement this laboratory plan

7. IMPLEMENTERS OF MALARIA LABORATORY PLAN

The lab plan is a joint intent to provide quality assured malaria diagnosis at all health facility. The laboratory plan will be implemented as per guidance of the national malaria laboratory steering committee. The key national implementers of this laboratory plan are:

1. EDCD,
2. NPHL and
3. VBDRTC

7.1 Epidemiology and Disease Control Division (EDCD)

National malaria elimination program is led by EDCD and it is responsible for the implementation of strategic plans, disease surveillance, diagnosis and disease prevention. The government has set target to obtain zero indigenous cases in 2022 and achieve malaria elimination by 2025.

EDCD is responsible for ensuring quality of laboratory commodities, supply chain management, supervision and monitoring, coordinating with NPHL and VBDRTC for conducting basic and refresher trainings and competency assessment of malaria microscopists, organizing review meetings, data management and over all coordination of the malaria programme including operationalization of this national laboratory plan.

Key activities/inputs for implementation of this plan:

- Procurement of RDTs, microscopy supplies

- Planning and coordination among all stake holders till the local level.
- Ensure effective implementation of the National Lab plan
- Support in the QA/QC of malaria microscopy
- Lot testing of RDTs
- Conduct community-based testing of malaria
- Allocate resources for implementation of the laboratory plan.

7.2 Vector Borne Disease Research and Training center (VBDRTC)

VBDRTC has been extensively involved in malaria and other vector borne diseases since its establishment in 1979. This is the only central office under Ministry of Health and Population that has its entire scope of area mainly focused on vector borne disease related trainings, research, surveys and vector biology studies. VBDRTC has been conducting basic and refresher malaria microscopic trainings for laboratory personnel across the country since the beginning. VBDRTC has served as malaria reference center since its inception and has accumulated ample of experience in conducting trainings and quality assurance than anywhere in the country.

VBDRTC possesses all required infrastructures such as separate staining rooms, microscopy halls, training halls with continuous power back up and staff motivated and dedicated to run quality assurance. VBDRTC had conducted national competency and ECAMM with the support from WHO and EDCD in past years. It has maintained database of competency of microscopists enrolled in microscopy training. This institute has a facility to build the national slide banking center with a capacity of more than 10,000 slides. VBDRTC has also contributed cross-checking of slides during outbreak investigations and from case-based investigations.

Key activities/inputs for implementation of this plan:

- Training in basic/refresher microscopy
- Certification in National CAM
- Capacitate adequate HR for conducting microscopy and QA/QC
- Implement the QA/QC where necessary
- Carry out relevant researches for evidence-based interventions

7.3 National Public Health Laboratory (NPHL)

NPHL is apex body which is responsible for ensuring quality of all diagnostic laboratory services throughout the country. It has been involved in accreditation of medical laboratories, external quality assessment (EQA) of diagnostic services, training of laboratory personnel, and monitoring and supervision.

A national laboratory assessment conducted in 2017 has recommended for organization of external Quality Assessment (EQA) of malaria diagnosis. Malaria TWG meeting held on 13th September 2018 has decided to establish national reference laboratories for Malaria at NPHL.

Key activities/inputs for implementation of this plan:

- Develop the national malaria laboratory technical guidance and standards, standard operating procedures (SOPs), forms and formats for all activities related to ensuring a high quality of malaria microscopy.
- Coordinate and guide malaria laboratory services in accordance with the plan
- Ensure that the quality of laboratory services is maintained throughout the country through the established QA networks.
- Make inventory of available resources including trained staff, equipment such as microscopes, lab commodities and budget.
- Assign a national malaria QA focal person or coordinator.
- Collect data on current workload and assessing adequacy of resources with respect to the workload.
- Coordination with provincial reference laboratories, carry out an evaluation of the competency of available microscopists at all levels of the program.
- Coordinate for deployment of trained human resources (based on need of competency level and function of health facility in diagnosis and QA/QC system).
- Perform cross-checking of slides from provincial reference laboratories.
- Share malaria microscopy QA/QC results with national malaria program (EDCD) quarterly and making recommendations for further improvement.
- Provide support to national malaria program for specification, quantification and procurement of laboratory equipment, supplies and consumables.
- Develop malaria slide bank at national level following standard operating procedures developed by WHO.
- Develop monitoring and supervision plan and conducting monitoring visits to malaria testing sites including private sectors.
- Conduct malaria microscopy trainings as needed

8. MONITORING AND EVALUATION

The monitoring and evaluation framework outlines the processes, systems, and infrastructure involved in tracking and assessing the results of interventions and activities implemented under the National Lab Plan.

M&E of malaria lab plan should:

- i. Coordinate collection, processing, analysis and management of malaria laboratory data;
- ii. Verify whether activities have been implemented as planned;
- iii. Provide feedback to data providers, relevant authorities to improve decision making and future planning;
- iv. Monitor progress towards malaria program goals and objectives;
- v. Conduct periodic audits, both internal and external to evaluate performance based on indicators
- vi. Adjust activities, interventions and timelines according to results of the reviews

8.1 Monitoring and Supervision

The monitoring and supervision plan will be developed by each key stakeholder. Monitoring visits will be conducted at different levels including national, provincial and district/local level.

Each MCs will be visited at least twice in a year by a certified microscopist to monitor malaria microscopy activities at MCs. Adherence to SOPs for malaria microscopy, performance of malaria microscopist and training needs will be assessed during monitoring visits and required support will be provided to the microscopist during monitoring visits.

Health facilities performing RDTs will also be visited at least twice in a year by laboratory staff with adequate knowledge about RDTs and provided with required support and feedback.

8.1.1 Indicators:

The main outcome of the national program for strengthening diagnostic services is the ‘percentage of suspected malaria cases tested for malaria. Universal access to malaria diagnostics is reached when this indicator is close to 100%. The indicators (Table 1) can be calculated at various levels (health facility, district, provincial or national).

Table 1: Indicators for monitoring malaria diagnosis:

	Indicator	Numerator/denominator
1	Percentage of suspected malaria cases tested by RDT	Numerator: Number of patients tested by RDT × 100 Denominator: Number of suspected malaria cases
2	Percentage of suspected malaria cases tested by microscopy	Numerator: Number of patients tested by microscopy × 100 Denominator: Number of suspected malaria cases
3	Percentage of suspected malaria	Numerator: Number of patients tested by RDT and

	cases tested for malaria	microscopy $\times 100$
		Denominator: Number of suspected malaria cases
4	Percentage of health facilities reporting no stock-out of RDTs per month	Numerator: Number of health facilities reporting no stock-out of RDTs this month $\times 100$
		Denominator: Number of reporting health facilities receiving RDTs
5	Percentage of health facilities reporting no stock-out of key microscopy consumables	Numerator: Number of health facilities reporting no stock-out of key microscopy consumables $\times 100$
		Denominator: Number of reporting health facilities
6	Percentage of health facilities with at least one health worker trained in performing RDT for malaria	Numerator: Number of health facilities with at least one health worker trained in performing RDT for malaria $\times 100$
		Denominator: Number of reporting health facilities
7	Percentage of health facilities (HF) with at least one trained malaria microscopist	Numerator: Number of targeted HF with at least one trained malaria microscopist $\times 100$
		Denominator: Number of targeted HF

9. LABORATORY FINANCING:

The financing of the laboratory services must be a part of overall financing plan for malaria program under the EDCD. Laboratory services must be funded adequately through national and/or donor funding. All cost associated with quality assured diagnostics, diagnostic network establishment and quality assurance system including human resource must be detailed in budget and funded for effective implementation of this national laboratory Plan.

10. ANNEXURES:

All these of following documents will be included in the working document (SOPs) that will be prepared under the QA/QC steering committee.

1. *Selection of appropriate tools for malaria diagnosis at health facilities*
2. *Level of detection of malaria microscopy and RDTs*
3. *Relative importance of quality determinants in RDTs and microscopy for malaria diagnosis*
4. *WHO competency grading chart*
5. *Malaria laboratory activities planned for 2020-2022*
6. *Roles and responsibilities of national, provincial and peripheral health facilities in national malaria QA/QC*

Table 2: Selection of appropriate tools for malaria diagnosis at health facilities

Criteria	Clinical settings	RDT	Microscopy
Parasite density	Uncomplicated malaria	YES	YES
	Severe malaria at admission	Not alone	YES
	Follow-up of hospitalized severe malaria	NO	YES
Antigen persistence	Treatment failure of confirmed malaria	NO	YES
	Incomplete antimalarial treatment and/or unconfirmed malaria diagnosis	YES	YES
Electricity supply	Hospitals and health centers	YES	YES
	Health Posts and CHWs	YES	NO
Test duration	Heavy patient load	YES	Not alone
Technical skills	Limited training and supervision	YES	NO

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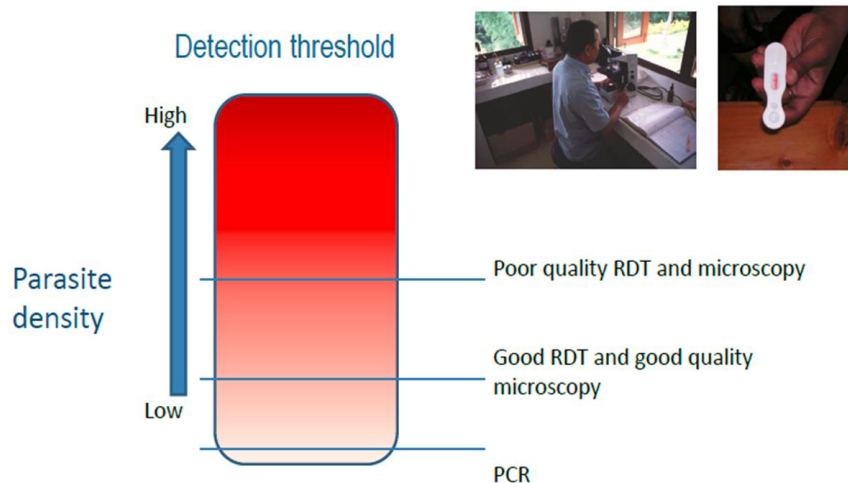


Figure 1. Level of detection of malaria microscopy and RDTs

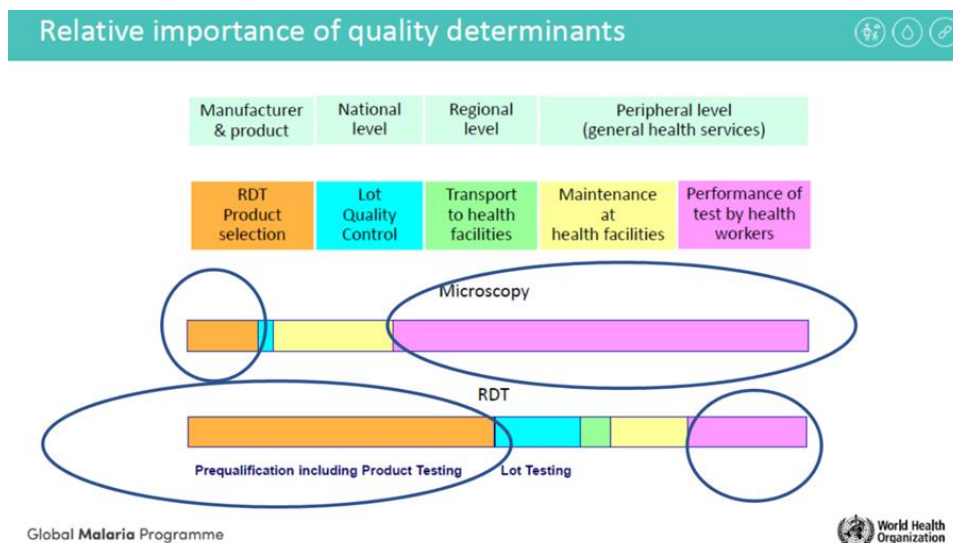


Figure 2. Relative importance of quality determinants in RDTs and microscopy for malaria diagnosis

Table 3: WHO COMPETENCY GRADING CHART

Accreditation level	Detection of parasitaemia	Species identification	Parasite quantitation (25% of true count)	False positive rate
Level 1 (<i>Expert</i>)	≥90%	≥90%	≥50%	≤2.5%
Level 2	80–<90%	80–<90%	40–<50%	≤5%
Level 3	70–<80%	70–<80%	30–<40%	≤10%
Level 4	<70%	<70%	<30%	≤20%

Source: Adapted from WHO levels of accreditation for malaria microscopy (WHO, 2009a).

Table 4. MALARIA LABORATORY ACTIVITIES (TABLE)

Table 1: Malaria laboratory activities planned for 2020-2025			
SN	Activities	Responsible	Remarks
1.	Diagnosis of malaria at different levels of healthcare facilities		
1.1	Identify health facilities performing malaria Microscopy. Those facilities will be considered as malaria microscopy centers (MCs) for national malaria program.	EDCD and NPHL	
1.2	Ensure availability of RDTs in peripheral healthcare facilities other than MCs	EDCD	Ongoing
1.3	Ensure provision of trained/certified malaria microscopist in each MC.	EDCD, DoHS	
1.4	Encourage use WHO-prequalified antigen-based malaria RDTs in private sector.	EDCD, NPHL	Ongoing
2.	Quality assurance/Quality Control of malaria microscopy:		
2.1	<i>National Level</i>		
2.1.1	Formation of national malaria laboratory technical committee	NPHL	

SN	Activities	Responsible	Remarks
2.1.2	An assessment to determine current situation of malaria QA/QC in Nepal.	EDCD, NPHL, VBDRTC	The assessment will identify provincial centers to carry out malaria QA/QC activities until the provincial reference laboratories become functional. The assessment will also help identify malaria microscopy centers in districts.
2.1.3	Identification of national malaria QA/QC focal person at National Public Health Laboratory (NPHL)	NPHL	
2.1.4	Deployment of at least three certified malaria microscopist (WHO level 1 or 2) at NPHL.	NPHL, DoHS	
2.1.5	Development, finalization and endorsement of malaria QA/QC guidelines/protocol and required recording/reporting forms and formats.	NPHL, EDCD, VBDRTC	
2.1.6	Orientation of provincial laboratory staff on national QA/QC guidelines.		
2.1.7	Distribution of guidelines, forms and formats to provincial reference laboratories and MCs along with a letter to participate in malaria QA/QC activities following national malaria QA/QC guidelines.	EDCD, NPHL	

SN	Activities	Responsible	Remarks
2.1.8	Cross-checking of slides received from provincial reference laboratories.	NPHL	Ongoing
2.1.9	Providing timely results and feedback of cross-checking to provincial reference laboratories following national guidelines.	NPHL	Ongoing
2.1.10	Conduct annual review meeting with provincial reference laboratories.	NPHL, EDCCD	Ongoing
2.1.11	Maintain malaria slide banking at central level.	NPHL, VBDRTC	Ongoing
2.2	<i>Provincial level</i>		
2.2.1	Formation of provincial malaria QA committee and assigning a provincial malaria QA focal person.	PPHL*	* <i>Provincial reference laboratory</i> Until the PPHLs become established and functional, these committees will be formed at provincial designated QA/QC centers to carryout QA/QC activities.
2.2.2	Deployment of at least two certified malaria microscopists at provincial reference laboratory (WHO level 1 or 2).	PPHL, PHD*	* provincial health directorate

SN	Activities	Responsible	Remarks
2.2.3	Orientation of MCs on national QA/QC guidelines, forms and formats	PPHL	
2.2.4	Cross-checking of slides received from MCs (through DHO)	PPHL	
2.2.5	Providing timely results and feedback of cross-checking to MCs (through DHO) following national guidelines.	PPHL	
2.2.6	Maintaining malaria slide banking at provincial level	PPHL	Ongoing
2.2.7	Conducting periodic review meetings with MCs	PPHL	Ongoing
2.3	<i>DHO</i>		
2.3.1	Collect QA/QC slides from peripheral healthcare facilities and send to provincial reference laboratory for cross-checking		Ongoing
2.3.2	Receive results of cross-checking from provincial laboratories and provide them to microscopic centers.		Ongoing
2.3.3	Provide support to microscopic centers to take corrective actions based on the recommendations provided by provincial laboratories.		Ongoing
2.4	<i>Microscopy centers (MCs)</i>		

SN	Activities	Responsible	Remarks
2.4.1	Participation in malaria microscopy QA/QC following national malaria QA/QC guidelines.	MCs, PPHL, NPHL	Ongoing
2.4.2	Completion of required QA/QC records and documentation.	MCs	Ongoing
2.4.3	Participation in review meetings organized by provincial reference laboratories.	MCs, PPHL	
2.4.4	Implementation of feedback received from provincial reference laboratories.	MCs	Ongoing
2.4.5	Collection of slides from lower peripheral healthcare facilities which perform RDTs only.	MCs	Ongoing
2.4.6	Examination of slides received and sending the results back to the facilities which perform RDTs only.	MCs	Ongoing
3	Quality assurance of RDTs		
3.1	<i>National Level</i>		
3.1.1	Advocacy for mandatory use of WHO-prequalified RDTs at all healthcare facilities using RDTs including public and private health facilities.	NPHL, EDCCD	Ongoing
3.1.2	Development and endorsement guidelines for quality assurance of RDTs at each level of storage and testing	NPHL	

SN	Activities	Responsible	Remarks
3.1.3	Coordination with WHO for participation in malaria RDT lot testing program organized by WHO	NPHL, WHO	
3.1.4	Participation in RDT Lot Testing program organized by WHO	NPHL, WHO	
3.1.5	Quantification and procurement of positive control wells (PCWs) for distribution to provincial storage facility and health facilities using RDTs.	EDCD, NPHL	
3.1.6	Distribution of PCWs to provincial storage facility and health facilities using RDTs with guidelines for using PCWs.	NPHL	
3.1.7	Compilation of results of PCW testing at provincial storage facility and health facilities using RDTs. Review results and take necessary actions.	NPHL	
3.2	<i>Provincial level</i>		
3.2.1	Facilitation in collecting sample RDTs from provincial storage facility and health facilities to send them to WHO's RDT lot testing program.	PPHL	
3.2.2	Facilitation in distribution of positive control wells (PCWs) to health facilities using RDTs	PPHL	
3.2.3	Collection of results of PCW proficiency testing at peripheral health facilities and provide necessary	PPHL	

SN	Activities	Responsible	Remarks
	support based on the results of PCW testing		
3.3	<i>Peripheral level</i>		
3.3.1	Participation in PCW proficiency testing organized by provincial reference laboratory, complete required documentation and submit results back to the provincial reference laboratory within the timeline stipulated by RDT QA guidelines.	Peripheral Health Facilities	
4	Training and certification of laboratory personnel		
4.1	Basic and refresher malaria microscopic trainings	VBDRTC, PPHL, NPHL	Ongoing
4.2	Malaria microscopy refresher trainings organized WHO	EDCD, WHO, NPHL, VBDRTC	
4.3	External competency assessment of malaria microscopists (ECAMM)	VDBRTC, NPHL, WHO	
4.4	National competency assessment of malaria microscopists (NCAMM)	VBDRTC, NPHL,	Annual
5	Supervision and monitoring		
5.1	Development and finalization of tool or checklist for conducting supervision and monitoring of MCs	Lab technical committee, NPHL	Supervision and monitoring will include outreach training and supportive supervision.

SN	Activities	Responsible	Remarks
5.2	Annual monitoring visits from national level to provincial level and MCs.	NPHL, EDCCD	Annual
5.3	Biannual monitoring visit from provincial/D(P)HO level to MCs.	PPHL	Biannual
5.4	In case of discrepant microscopy results in cross-checking, immediate coaching and mentoring of microscopist at MC.	PRL, NPHL	Ongoing
6	Maintenance of microscope		
6.1	Develop and implement mechanism for reporting breakdown and maintenance of microscopes at MCs.	NPHL	

Table 5. ROLES AND RESPONSIBILITIES OF NATIONAL, PROVINCIAL AND PERIPHERAL HEALTH FACILITIES IN NATIONAL MALARIA QA/QC

National Reference Center	Provincial Public Health Laboratory	DHO (District Health office)	Designated microscopic centers	Peripheral health facilities
Formation of provincial malaria QA committee and assigning a provincial malaria QA focal person. Making inventory of available resources including trained staff, equipment such as microscopes, lab commodities and budget in coordination with EDCD Developing and finalizing guidelines, standard operating procedures, forms and formats for all activities related to ensuring a high quality of malaria microscopy in coordination with EDCD Establishment of provincial malaria QA/QC lab with a team of at least two lab personnel (WHO level 1-2) for malaria microscopy Ensuring availability of guidelines, SOPs, forms and formats at SDPs.	Formation of provincial malaria QA committee and assigning a provincial malaria QA focal person Deployment of at least two certified malaria microscopists at provincial reference laboratory (WHO level 1 or 2) Orientation of MCs on national QA/QC guidelines, forms and formats Cross-checking of slides received from MCs (through DHO) Providing timely results and feedback of cross-checking to MCs (through DHO) following national guidelines Maintaining malaria slide banking at provincial level	Collect QA/QC slides from peripheral healthcare facilities and send to provincial reference laboratory for cross-checking Receive results of cross-checking from provincial laboratories and provide them to microscopic centers. Provide support to microscopic centers to take corrective actions based on the recommendations provided by provincial laboratories.	Participation in malaria microscopy QA/QC following national malaria QA/QC guidelines Routine cross-checking of slides obtained from peripheral health facilities and send back the feedback to the health facilities. Any discrepancies in test results should be referred to	Perform malaria laboratory diagnosis following SOPs Timely diagnosis and recording and reporting Maintain all positives and negative slides Send all positives and 5% negatives to designated microscopic centers Participate in RDT quality assurance and

Supporting in national slide banking. Planning of malaria activities in line with national malaria program. Facilitating distribution laboratory equipment, consumables and supplies to SDPs. Cross-checking of slides received from provincial levels and occasionally from all levels at nationwide whenever necessary. Providing regular feedback to Ensuring adequate recording and reporting in coordination with EDCD Sharing results of cross-checking with EDCD on a regular basis. Conducting periodic review meetings in coordination with EDCD Conducting onsite training and supportive supervision in coordination with EDCD	Cross-checking of slides received from district health offices and SDPs within the province. Providing regular feedback to district health offices and SDPs (Service delivery points). Sharing results of cross-checking with NPHL on monthly basis. Send 100% all positive slides and 5% negative slides for further rechecking to national reference laboratory. Collection of slides from lower peripheral healthcare facilities which perform RDTs only Examination of slides received and sending the results back to the facilities which perform RDTs only Conducting basic and refresher training to public and private sectors. Maintain database of all microscopists and their competencies and QA/QC performances Supporting in national slide banking.	Ensure laboratory commodities and supportive supervisions Participate in review meetings Collection of slides from lower peripheral healthcare facilities which perform RDTs only Examination of slides received and sending the results back to the facilities which perform RDTs only Participate in quality assurance of RDTs Maintain inventories and documentation of all activities	higher levels immediately for confirmation Send 100% of all positives and 5% of negatives to higher levels for cross-checking Collection of slides from lower peripheral healthcare facilities which perform RDTs only Examination of slides received and sending the results back to the facilities which perform RDTs only Completion of required QA/QC records and documentation	giemsa stain microscopy Participate in periodic review meetings Participate in on site proficiency testing and basic and refresher malaria microscopy training Strictly follow SOPs of malaria diagnosis Maintain lab commodities and equipment maintenance log book Support in Slide banking Support in slide
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Facilitating distribution of commodities and supplies to SDPs and to transport slides for cross-checking from SDPs to provincial reference laboratory. Run TOTs and other competency assessments in coordination with training centers and national implementation bodies Collection of slides visiting in NPHL in routine diagnosis from all levels Examination of slides received and sending the results back to the facilities which perform RDTs only or require confirmation in discrepant test results Advocacy for mandatory use of WHO-prequalified RDTs at all healthcare facilities using RTDs including public and private health facilities. Development and endorsement	Participate in RDT QA/QC testing as per the national QA QC Ensure proper Supply and chain management; laboratory commodities and strengthening laboratories and training Conduct on-site proficiency testing/ Outreach Supervision and monitoring Participate in annual review meetings Conduct provincial review meetings periodically Follow the implementation of corrective actions and provide training and technical support		Maintain database of all microscopists and their competencies and QA/QC performances Support in National and provincial Slide banking Participate in training and also record list of people which are underperforming and performing satisfactorily Recommend the list for microscopy training Participate in on-site proficiency	collection, examination and refer and coordinate with the higher levels for cross checking, confirmation and reporting Others as directed per the national program
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guidelines for quality assurance of RTDs at each level of storage and testing Coordination with WHO for participation in malaria RDT lot testing program organized by WHO Participation in RDT Lot Testing program organized by WHO Conduct QA/QC of RDTs in coordination with EDCCD, WHO and stakeholders Quantification and procurement of positive control wells (PCWs) for distribution to provincial storage facility and health facilities using RDTs. Distribution of PCWs to provincial storage facility and health facilities using RDTs with guidelines for using PCWs.			testing and Participate in RDT quality assurance Participation in review meetings organized by provincial reference laboratories Implementation of feedback received from provincial reference laboratories Follow the implementation of corrective actions and provide training and technical support	
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Compilation of results of PCW testing at provincial storage facility and health facilities using RDTs. Review results and take necessary actions. Follow the implementation of corrective actions and provide training and technical support				
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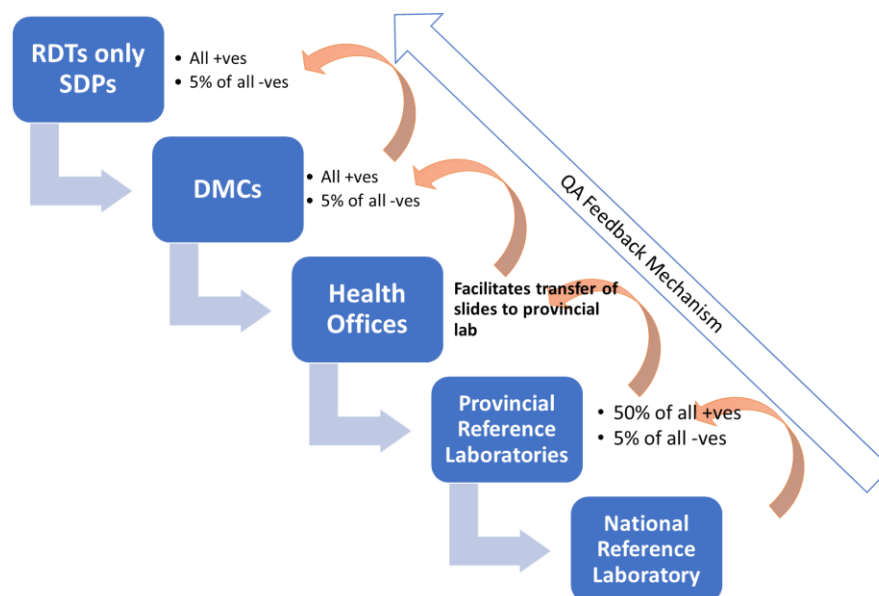


Figure 4. Diagram showing flow of slides for cross-checking from peripheral healthcare facilities to national reference center and QA feedback mechanism

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