Federal Democratic Republic of Ethiopia
Ministry of Health

Malaria Laboratory Diagnosis External Quality Assessment Scheme Guidelines

2nd Edition

Ethiopian Public Health Institute
Federal Ministry of Health
November, 2017
Ethiopia

Federal Democratic Republic of Ethiopia
Ministry of Health

Malaria Laboratory Diagnosis External Quality Assessment Scheme Guidelines

2nd Edition

Ethiopian Public Health Institute
Federal Ministry of Health
January 2018
Ethiopia

FOREWORD

The Ethiopian Public Health Institute (EPHI) is mandated by the Federal Ministry of Health (FMOH) to protect and promote the health of Ethiopian people by addressing priority public Health and Nutrition problems through problem-solving research, public health emergency management, establishing and maintaining quality laboratory system. To realize the stated mission, EPHI is working hard to improve the quality of laboratory services across the health system in the country to tackle all diseases in general and the major diseases including HIV/AIDS, tuberculosis and malaria in particular.

Malaria is among the leading cause of morbidity and mortality in Ethiopia. *Plasmodium falciparum* and *P. vivax* are the two most dominant malaria parasites in Ethiopia and are prevalent in all malaria endemic areas with their relative frequency varying in time and space within a given geographical range. Approximately 60% of the total population lives in areas at risk of malaria. According to Ethiopia's Federal Ministry of Health (FMOH), in 2009 Ethiopian Fiscal Year (EFY), the total number of laboratory confirmed plus clinical malaria cases were 1,747,251. In particular, the monthly pattern showed an increase in the first five months of the fiscal year reaching the highest peak in November, followed by a decrease until April. A total of 374 deaths were recorded in the same period, with a Case Fatality Rate (CFR) of 0.02%.

Out of the total 1,747,251 malaria cases reported in the fiscal year, 1, 276,371 (73%) were confirmed by either microscopy or rapid diagnostic tests (RDT), out of which 1, 059,829 (83%) were Plasmodium falciparum (PF) and 216,542(17%) were Plasmodium vivax (PV). When we look at the trend with the regard to parasite type over the year, *Plasmodium falciparum* is steadily increasing while *P. vivax* is decreasing.

In 2003 to increase population's access to health, the FMOH launched a countrywide program – Health Service Extension Program (HSEP) that focuses on the delivery of 17 essential health packages. Malaria has been one of the packages that are under implementation with enhanced advocacy, communication and social mobilization that dramatically increased the number of service seekers for both diagnostic and treatment services. The FMOH has developed the 2014-2020 National Strategic Plan (NSP) which is built on the achievements of 2011-2015 strategic plan, and, through sustained control, will move towards malaria elimination through an integrated community health approach. This will be achieved through continued provision of malaria prevention tools (LLINs and IRS). Increased diagnosis and case detection, increased access to treatment, and will only be possible as part of a community mobilization effort.

A successful Malaria Prevention and Control Program is dependent on availability of high quality laboratory diagnostic services. Early diagnosis and prompt treatment is one of the main strategies in malaria prevention and control. Malaria diagnosis based on clinical signs and symptoms alone is not specific and usually leads to excessive use of anti-malarial drugs. Therefore parasite-based diagnosis is an important part of the case management of malaria. The National Laboratory Quality System (NLQS) Operational Plan was developed by EPHI in December 2006 to establish a system for ensuring high quality laboratory services for diseases such as HIV, TB, and malaria. In order to support and facilitate, quality assurance of blood film microscopy and RDT for malaria, and particularly focusing on the implementation of external quality assessment (EQA), this comprehensive Malaria Laboratory Diagnosis EQA scheme Guidelines has been developed. This standalone guideline serves as framework for implementation of National EQA scheme for malaria laboratory diagnosis. Competence in the area of microscopy and RDT is a necessity for laboratory technicians, health extension workers and other health workers providing service to malaria cases. The use of this guideline alongside other contemporary guidelines will be instrumental in the national effort to strengthen integrated quality assurance of laboratory activities and ultimately improve quality of life of the general public.

EPHI calls all partners – governmental, non-governmental and private alike to provide support in the proper use of this guideline in malaria diagnostic laboratories the future strengthen the fight against Malaria.

Ebba Abate (PhD)

Director General, Ethiopian Public Health Institute (EPHI)

ACKNOWLEDGMENT

The development and the revision of this standalone Malaria Laboratory Diagnosis External Quality Assessment Implementation Manual was made possible through contribution of the professionals and institutions listed below:

The following individuals are acknowledged for Critical review and revision of the guideline:

Abnet Abebe	EPHI
Gonfa Ayana	EPHI
Adisu Kebede	EPHI
Habtamu Asrat	EPHI
Desalegn Tesema	EPHI
Abeba G/Tsadik	EPHI
Adino Desale	EPHI
Sindew Mekasha	EPHI
Tesfay Abreha	ICAP in Ethiopia
Leykun Demeke	ICAP in Ethiopia
Fanuel Zewdu	ICAP in Ethiopia
Abebe Tadesse	ICAP in Ethiopia
Mekonnen Tadesse	ICAP in Ethiopia
Daniel W/senbet	ICAP in Ethiopia
Kinde Mulatu	ICAP in Ethiopia

The following individuals are acknowledged for developing the first edition of this guideline.

Gudeta Tibesso	EPHI
Getachew Belay	EPHI
Bereket Hailegiorgis	ICAP in Ethiopia
Leykun Demeke	ICAP in Ethiopia
Sintayehu G/Sellasie	ICAP in Ethiopia
Gonfa Ayana	EPHI
Leulseged Takele	EPHI
Markos Sleshi	EPHI

Moges Kassa	EPHI
Sindew Mekasha	EPHI
Adisu Kebede	EPHI
Hussien Mohammed	EPHI
Tilahun Muchie	EPHI
Abnet Abebe	EPHI
Zenebe Melaku	ICAP in Ethiopia
Samuel Girma	ICAP in Ethiopia
Richard Reithinger	USAID/PMI Ethiopia
Yamo Ouma	IMaD/AMREF
Nicole Whitehurst	IMaD/MCDI

The generous financial and technical support of ICAP at Columbia University through funding from PMI Ethiopia was paramount importance to do serial expert and consultative meetings to revise this guideline. We are indebted to PMI for covering the cost of printing the guidelines.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ABBREVIATIONS

ACT	Artemisinin Based Combination Therapy
AMREF	African Medical and Research Foundation
DNA	Deoxyribose Nucleic Acid
EFY	Ethiopian Fiscal Year
EPHI	Ethiopian Public Health Institute
EQA	External Quality Assessment
FIND	Foundation for Innovative New Diagnostics
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GoE	Government of Ethiopia
HIV	Human Immunodeficiency Virus
HEWs	Health Extension Workers
HEWS	Health Extension Worker Supervisor
HSDP	Health Sector Development Program
HSEP	Health Service Extension Program
IPTp	Intermittent Preventive Treatment of Pregnant women
IRS	Indoor Residual Spray
ITNs	Insecticide Treated Bed Nets
MCDI	Medical Care Development International
NEQAS	National External Quality Assurance Scheme
NLQS	National Laboratory Quality System
RLCBD	Regional Laboratory Capacity Building Directorate
NRL	National Reference Laboratory
PCR	Polymerase Chain Reaction
Pf	*Plasmodium falciparum*
PMI	President's Malaria Initiative

PT	Proficiency Test
Pv	*Plasmodium vivax*
QA	Quality Assurance
QBC	Quantitative Buffy Coat
QC	Quality Control
QI	Quality Improvement
QO	Quality Officer
RDT	Rapid Diagnostic Tests
REQAS	Regional External Quality Assessment Scheme
RRL	Regional Reference Laboratory
SOP	Standard Operating Procedure
TB	Tuberculosis
TOT	Training of Trainers
USAID	The United States Agency for International Development
WHO	World Health Organization

1 INTRODUCTION

1.1 Background

Malaria is caused by a parasite called *Plasmodium*, which is transmitted via the bite of infected female anopheles mosquitoes. In the human body, parasites multiply in the liver, and then infect red blood cells. Symptoms of malaria include fever, headache, and vomiting, and usually appear between 10 and 15 days after an infected mosquito bite. If not treated, malaria can quickly become life-threatening by disrupting the blood supply to vital organs.

Malaria is a serious public health problem in many parts of the world, exacting an unacceptable toll on the health and economic welfare of the world's poorest communities. There were large reductions in the number of malaria cases and deaths between 2000 and 2015. According to the latest estimates, between 2000 and 2015, malaria case incidence was reduced by 41% and malaria mortality rates by 62%. At the beginning of 2016, malaria was considered to be endemic in 91 countries and territories, down from 108 in 2000. Much of the change can be attributed to the wide-scale deployment of malaria control interventions. Despite this remarkable progress, malaria continues to have a devastating impact on people's health and livelihoods. Updated estimates indicate that 212 million (range 148–304 million) cases occurred globally in 2015, leading to 429 000 deaths (range 235 000–639 000), most of which were in children aged under 5 years in Africa. Recognizing the need to hasten progress in reducing the burden of malaria, WHO developed the Global Technical Strategy for Malaria 2016–2030, which sets out a vision for accelerating progress towards malaria elimination. The WHO strategy is complemented by the Roll Back Malaria advocacy plan, Action and investment to defeat malaria 2016–2030.

Malaria is among the leading cause of morbidity and mortality in Ethiopia. *Plasmodium falciparum* and *P. vivax* are the two most dominant malaria parasites in Ethiopia and are prevalent in all malaria endemic areas with their relative frequency varying in time and space within a given geographical range. The major malaria vector incriminated in Ethiopia is *Anopheles arabiensis;* in some areas *A. pharoensis*, *A. funestus* and *A. nili* also play minor role in transmission of malaria. Approximately 60% of the total population lives in areas at risk of malaria. According to Ethiopia's Federal Ministry of Health (FMOH), in 2009 Ethiopian Fiscal Year (EFY), the total number of laboratory confirmed plus clinical malaria cases were 1,747,251. In particular, the monthly pattern showed an increase in the first five months of the

fiscal year reaching the highest peak in November, followed by a decrease until April. A total of 374 deaths were recorded in the same period, with a Case Fatality Rate (CFR) of 0.02%.

Out of the total 1,747,251 malaria cases reported in the fiscal year, 1, 276,371 (73%) were confirmed by either microscopy or rapid diagnostic tests (RDT), out of which 1, 059,829 (83%) were Plasmodium falciparum (PF) and 216,542(17%) were Plasmodium vivax (PV). When we look at the trend with the regard to parasite type over the year, *Plasmodium falciparum* is steadily increasing while *P. vivax* is decreasing.

The main objective of the malaria prevention, control and elimination program in Ethiopia is to reduce morbidity and prevent mortality by applying intervention strategies that are suited to the local epidemiological situation of the disease. Early diagnosis and prompt treatment is one of the main strategies in malaria prevention and control.

Malaria diagnosis based on clinical signs and symptoms alone is not specific and usually leads to excessive use of anti-malarial drugs. Therefore parasite-based diagnosis is an important part of the case management of malaria particularly in a context with multiple species, and WHO recommends that the demonstration of parasites should form the basis for treating malaria in all cases except young children in areas of very high endemicity and during the control phase of malaria epidemics and emergencies.

There are different methods for detecting malaria parasites, including malaria microscopy, rapid diagnostic tests (RDTs; for detection of parasite antigens), enzymatic immunoassays or immunofluorescence techniques for detection of antibodies to malaria, Quantitative Buffy Coat (QBC) and Polymerase Chain Reaction (PCR; for malaria parasite DNA detection). PCR is currently the most accurate test and can identify low levels of infection not detectable by other methods. However, logistical and cost constraints have prevented this approach to be used routinely in an operational setting.

The diagnosis of malaria by conventional microscopy remains the gold standard for malaria diagnosis; although it requires highly-skilled personnel and may have a lower sensitivity than the recent molecular techniques. Microscopy is inexpensive (once the microscope is purchased), accurate and reliable, and can be used for species differentiation, parasite quantification, management of severe disease and investigating treatment failures. Maintaining a proper setting and standards of competency of laboratory personnel are vital parts of malaria microscopy performance. Although RDTs can provide rapid results at health post level, evidence shows that current RDT accuracy in the field is variable for

reasons such as lack of RDT lot testing after purchasing, relatively short shelf life (i.e. 18 months on average),and exposure to high temperatures during transport and storage.

The National Laboratory Quality System (NLQS) Operational Plan was developed by EPHI in December 2006 to establish a system for ensuring high quality laboratory services for diseases such as HIV, TB, and malaria. The development of this external quality assessment guideline for both malaria microscopy and malaria RDTs is important to establish External Quality Assessment (EQA) scheme for malaria diagnosis at different levels of the health care system.

An acceptable malaria microscopy and RDT service should provide results that are consistently accurate and timely enough to have a direct impact on treatment. This requires a comprehensive and active EQA scheme. This guideline is designed primarily to assist managers of malaria control programs and health facility based laboratory services to develop and maintain a sustainable EQA scheme on malaria Microscopy and RDTs.

Health facilities at all level of the tier system that are involved in malaria case management must participate in EQA. This extend from health posts staffed by Health Extension Workers (HEWs) to health centers and district/regional/referral/federal hospitals, and health facilities must be networked to the next level health facility to implement EQA activities in a sustainable fashion.

The purposes and benefits of introducing an EQA scheme are multiple and of mutual interest to both organizers and participants. The scheme monitors performance of each testing point over time, and identifies those testing facilities that require interventions to improve and bring their performance up to the accepted quality standard.

1.2 Quality Assurance (QA) of Malaria Microscopy and RDTs

QA is a system designed to improve the reliability and efficiency of laboratory services. The components of a QA scheme for malaria diagnosis are:

a) **Quality Control (QC):** A systematic internal monitoring of work practices, technical procedures, equipment, and materials including quality of stains.

b) **External Quality Assessment (EQA):** A process which allows participant laboratories to assess their capabilities by comparing their results with those of other laboratories in the network. This can be achieved through panel testing or blinded rechecking of slides for microscopy; and review of laboratory performance by on-site supervision for both microscopy and RDTs.

c) **Quality Improvement (QI):** A process by which the components of microscopy and RDT diagnostic services are analyzed with the aim of identifying and permanently correcting any deficiencies. Data collection, data analysis, and creative problem solving are skills used in this process.

The primary aim of the malaria microscopy and RDT QA scheme are to ensure the service is:

- Managed by competent and motivated staff.
- Supported by effective training and supervision that maintains a high level of staff competency and performance.
- Supported by a logistics system that provides and maintains an adequate and uninterrupted supply.

The specific **objectives** of the QA scheme for malaria diagnosis are to:

- Improve the overall performance of professionals at each level of the laboratory services.
- Sustain the highest level of accuracy (in sensitivity and specificity) in confirming the presence of parasites.
- Monitor systematically laboratory procedures, reagents and equipment.

A QA scheme must be:

- Realistic, feasible and sustainable.
- Compatible with the different situations and needs of each country.
- A catalyst for change to a culture of quality.
- Able to promote the best quality in the prevailing circumstances.

A QA scheme should appropriately recognize and accredit good performance; identify laboratories and laboratory personnel with serious problems that lead to poor performance; establish regional or national benchmarks for quality diagnosis; and establish central monitoring of indicators including accuracy, equipment and reagent performance, stock control and workload. This guideline is prepared to standardize EQA for microcopy and RDT along the health delivery system of the Ethiopian FMOH.

2 EQA METHODS AND LABORATORY NETWORK FOR MALARIA LABORATORY DIAGNOSIS

There are three EQA methods for evaluating performance of malaria laboratory diagnosis namely panel testing, blinded rechecking and Onsite evaluation.

2.1 Panel Testing

Panel testing refers to the process by which laboratories (known as the "test laboratories") performs malaria microscopy on a set of prepared slides received from the National and Regional Laboratories. This exercise can check both the laboratories' staining quality as well as the ability of technicians to recognize and identify malaria parasites present.

Panel slides to be prepared for EQA consist of 10 stained slides but in cases involving poor staining performance at a test site, an alternative approach is to include both stained and unstained films so as to be able to evaluate proficiency in malaria microscopy. The unstained panel slides should be examined within a week of the smear prepared. The panel should consist of high-quality blood slides, representing all malaria parasite species prevalent species in the country, various parasite densities, mixed infections and *negative* slides. The National or Regional Laboratories must provide feedback to the test laboratories, including scoring for accuracy of the results as well as suggestions as to the likely explanations for any errors and ways to improve performance. A major advantage of panel testing is that it provides a rapid picture of the proficiency of many laboratories in Ethiopia and specific Regional States. Distribution of the same panel to different laboratories will identify sites most in need of improvement and will allow comparison between sites. Panel testing is conducted three times per year.

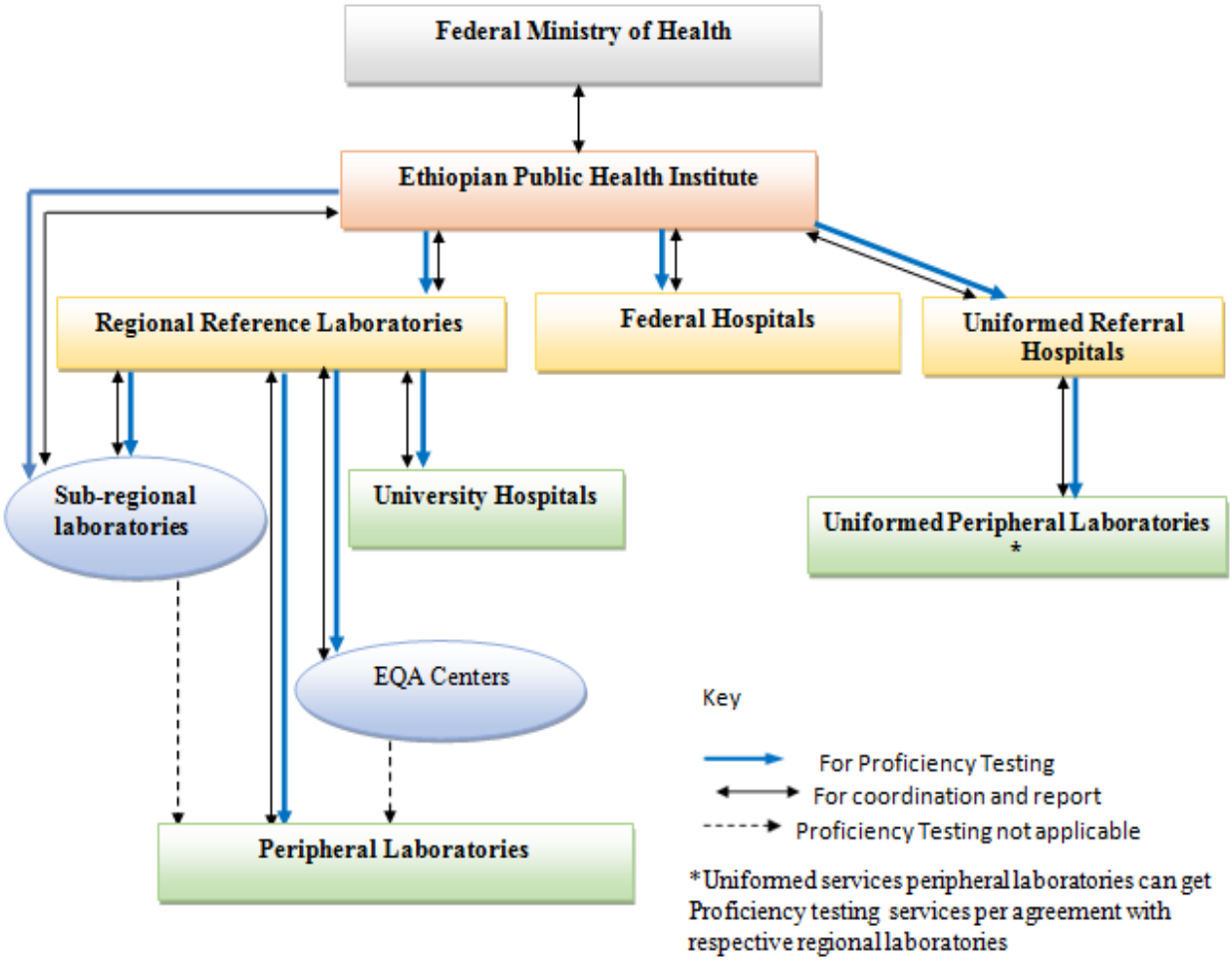


Figure 1: Structure of Panel testing

2.1.1 Roles and responsibilities

2.1.1.1 Ethiopian Public Health Institute

- Prepare well characterized and validated blood film slides and distribute to RRLs, Sub Regional Laboratories, Federal Hospitals, Uniformed Referral Hospitals, and Tikur Anbesa specialized and teaching hospital.
- Prepare and send feedback results to RRLs, Sub Regional Laboratories, Federal Hospitals, Uniformed Referral Hospitals, and Tikur Anbesa specialized teaching hospital and other authorized bodies within two weeks.

- Follow the implementation of corrective actions and provide training and technical support
- Present summary report of PT performance to national laboratory technical working group one month after each of the PT cycles when found appropriate
- Provide consolidated bi-annually summary report to FMOH
- Organize annual review meetings.

2.1.1.2 Regional Reference Laboratories

- Prepare or borrow well characterized and validated blood film slides and distribute to sub-regional laboratories, EQA Centers, health facility laboratories which are not participating in blinded rechecking, and health facility laboratories in malaria elimination districts.
- Prepare or borrow well characterized and validated blood film slides and distribute to uniformed peripheral laboratories if requested for support.
- Prepare and send feedback to participant laboratories within two weeks of result receipt.
- Participate in panel testing organized by EPHI
- Take corrective actions for identified gaps and report to EPHI within two weeks.
- Follow the implementation of corrective actions and provide training and technical support to, sub-regional laboratories.
- Provide consolidated summary report to RHB and EPHI after each round of PT implementation in the region
- Organize review meetings annually.

2.1.1.3 Sub-Regional Laboratories

- Participate in PT organized by EPHI and/or RRLs
- Take corrective actions on identified gaps and report to EPHI and/or RRLs within two weeks.

2.1.1.4 Uniformed services (Army, Federal Police and Federal Prison hospital laboratories)

- Prepare or borrow well characterized and validated blood film slides and distribute to peripheral laboratories which are not participating in blinded rechecking
- Participate in PT program organized by EPHI if not involved on blinded rechecking

- Take corrective actions for the identified gaps and report to EPHI within two weeks.
- Send feedback results to participant laboratories within two weeks after the arrival of the slides.
- Follow the implementation of corrective actions and provide technical support to participant peripheral laboratories.
- Co-Work with RRL to distribute PT to uniformed peripheral laboratories.
- Provide consolidated bi-annually summary report to EPHI.

2.1.1.5 Federal hospital Laboratories

- Participate in PT program organized by EPHI.
- Take corrective actions on the identified gaps and report to EPHI within two weeks.

2.1.1.6 Peripheral Laboratories

- Participate in PT conducted by RRLs /uniformed referral hospitals
- Take corrective actions on the identified gaps and report to EPHI/RRLs/uniformed service laboratories within two weeks

2.1.2 Source of Panel Slides

Panel slides should be prepared and available both at National and Regional Laboratories. Slide banks should contain, as a minimum, slides of all the malaria species found in Ethiopia, as well as blood slides that have been confirmed as malaria *negative*. The number of slides of each category should be based on the relative parasite prevalence encountered by the malaria control program. The size of the bank must be determined by a needs assessment, characteristics of the QA system and available resources.

2.1.3 Registration of Participant Laboratories

Health facility laboratories at all levels of the public health laboratory system in the public and private sectors which provide malaria microscopy are eligible to participate in the panel testing. The health facility submitting the registration form (annex A) for participating in the PT scheme will receive a unique code number, which is a common one to all NEQAS activities.

2.1.4 Design and Production of Panel Slides

Slides for PT use should be prepared with a standardized method where all slides are characterized and validated by a minimum of six expert readers (WHO level 1) and molecular techniques. The established national slide bank is a resource center for getting PT slides for this purpose. PT slides may be prepared at regional level which could be validated only by the available expert readers and molecular techniques. PT slides will contain 10 stained slides composed of malaria negative and positive slides with different species, stage, and density.

2.1.5 Packaging and Shipment of Slides

Slides will be packed for distribution to the participant laboratories using standard procedures for handling hazardous material. The reporting formats, instruction letters and other additional information will be packed separately. The PT slides shipped from the national archive for the EQA program should be returned together with the results to the National/Regional EQA coordinating centers. Shipment of slides and results will be conducted using appropriate courier system.

2.1.6 Analysis and Feedback

Data entry, cleaning and analysis will be conducted at national and regional levels after receiving of results. Feedback for participant laboratories (see Annex B.3) will be sent within 15 days up on scoring the results. The scoring system is explained in Tables 1 to 3. A final summary report will be discussed and improvement plan will be developed for appropriate corrective actions.

Result Scoring for Panel Testing

Table 1 Scoring on Panel Slides

Key diagnostic Criteria	Value
Positive slide reported as *negative* or vice versa	0 points per slide
Positive slide reported correctly as *positive*	3 points per slide
Positive slide reported with correct parasite species identification	3 points per slide
Positive slide reported with correct parasite stage identification	2 points per slide
Positive slide reported with correct parasite load	2 points per slide
Negative slide report correctly *negative*	10 points per slide

NB: * *Scoring on each of the 10 panel slides worth 10 points.*

** For parasite load count with WBC method in thick blood film, variation up to ± 25% of the mean is acceptable.

Table 2 Interpretation of Scoring Panel Slide Results

Score per slide	Definition	
	Correct	**Incorrect**
10	• Parasite species identification • Parasite stage identification • Parasite Load	
10	• Negative slide report correctly.	
8	• Parasite species identification • Stage identification	• Parasite load
8	• *P*arasite species identification • Parasite Load	• Parasite stage identification
6	• *Parasite species* identification	• Stage identification • Parasite load
5	• Parasite load	• Parasite species identification • Stage identification
5	• Parasite stage identification	• Parasite species identification • Parasite load
0		• Positive report as negative or vice versa.

Table 3 Grading of Laboratory Performance Based on Result of Panel Slides

Grading Laboratory Performance	**Cumulative Score**	**Action**
Excellent	≥90%	• Congratulate staff for exemplary performance

Very Good	80<90%	• Staff should be congratulated for very good performance and told to 'maintain it'.
Good	70<80%	• Staff should be congratulated for good performance and the need for 'further improvement' • Check staff competency • Consider on the job training based on staff's weakness • Check reagent quality • Check the microscope
Poor	≤70%	• Staff should be informed of poor and the need for • 'immediate action for improvement' • Arrange immediate on-site supervision. • Check staff competency • Consider on the job training based on staff's weakness • Check Reagent quality • Check the Microscope • Regular follow-up for corrective action

2.2 Blinded Rechecking

Blinded rechecking refers to the process by which a random selection of slides collected from the "testing" laboratories is reexamined at a higher level laboratory. Slides are checked for quality of blood film preparation, quality of staining, and accuracy of the result. Rechecking reflects the true performance of laboratories offering routine diagnostic services at health facility level. The purpose of the exercise is to allow a statistically valid assessment of the proficiency of the peripheral laboratories

Rechecking may detect malaria misdiagnosis in routine work and assess the overall quality of testing. This should not be considered a criticism of the person who performed the routine examination. Misdiagnosis in routine examination is frequently caused by different reasons such as high workload, poor equipment and not necessarily lack of skill by the reader. Each round of rechecking must be followed by feedback in the form of written report, showing details of incorrect scorings and offering suggestions for quality improvement (corrective actions).

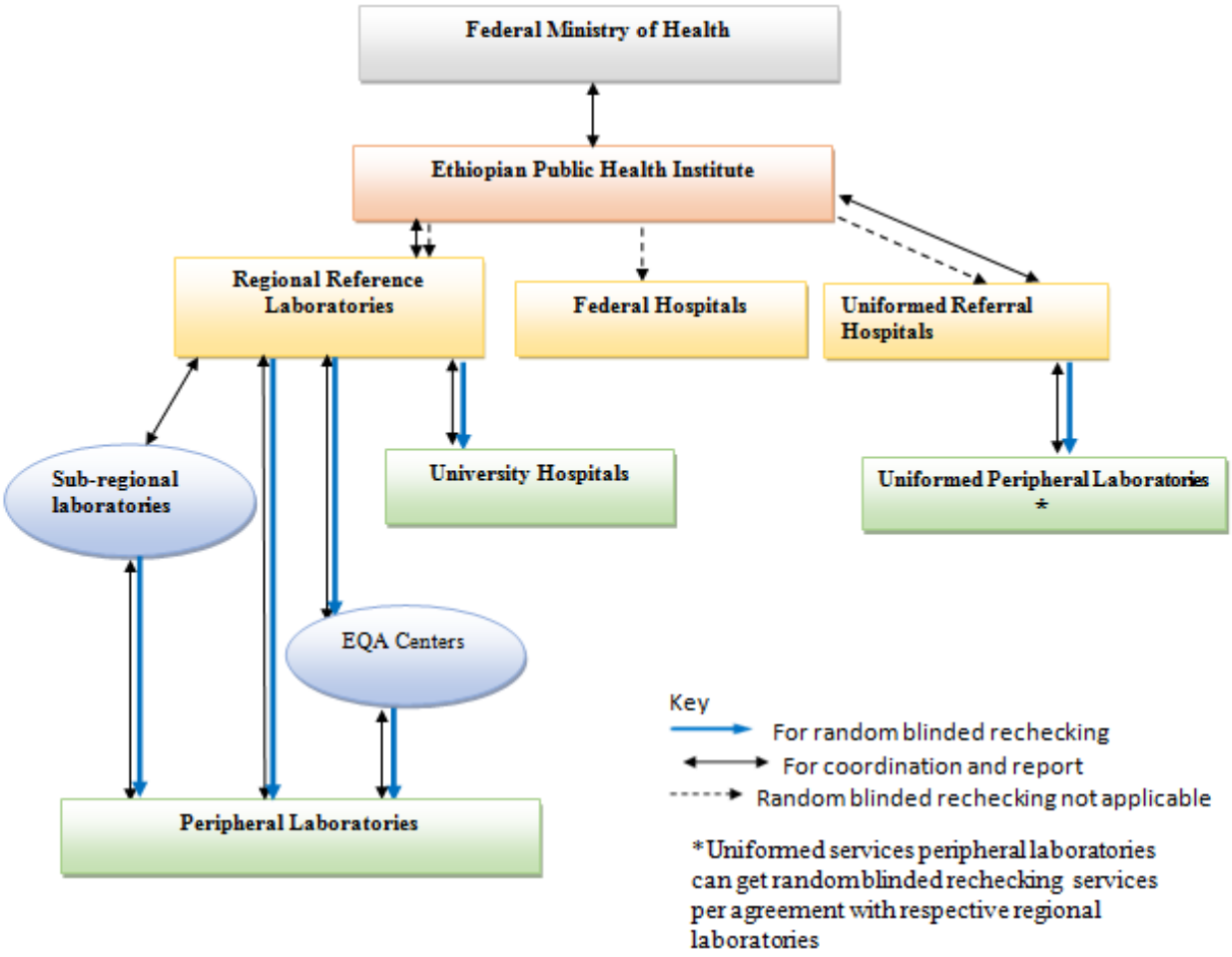


Figure 2: Structure of random blinded rechecking

2.2.1 Roles and Responsibilities

2.2.1.1 Ethiopian Public Health Institute

- Coordinate the implementation of blinded rechecking program in the country
- Follow the implementation of corrective actions and provide training and technical support.
- Compile and present summary reports on the program implementation to the national laboratory technical working group when found necessary
- Provide consolidated report annually to the FMOH
- Organize annual review meetings

2.2.1.2 Regional Reference Laboratories

- Coordinate the implementation of blinded rechecking program in their respective region
- Perform blinded rechecking for University Hospitals, EQA center laboratories and peripheral laboratories (which are not covered by EQA centers and sub-regional laboratories).
- Conduct blind rechecking for uniformed peripheral laboratories if requested a support by uniformed services.
- Resolve discrepant blinded rechecking results from EQA centers and sub-regional laboratories
- Send feedback results to participant laboratories within two weeks after the arrival of the slide at RRL.
- Follow the implementation of corrective actions and provide training and technical support to participant laboratories in their respective region.
- Provide consolidated report quarterly to RHB and EPHI
- Organize annual review meetings.

2.2.1.3 Sub-regional and EQA Center Laboratories

- Participate in blinded rechecking program organized by RRLs (Not applicable for sub-regional laboratories).
- Sub regional and EQA Center Laboratories take corrective actions and report to RRLs.
- Perform blinded rechecking to peripheral laboratories.
- Send feedback results to participant laboratories within two weeks after the arrival of the slides.
- Follow the implementation of corrective actions and provide technical support to participant peripheral laboratories.
- Store and select positive and negative blood film slides as indicated in this guideline (applicable only for EQA center laboratories)
- Provide consolidated report quarterly to RRLs

2.2.1.4 Uniformed services (Army, Federal Police and Federal Prison hospital laboratories)

- Perform blinded rechecking to peripheral laboratories.
- Send feedback results to participant laboratories within two weeks after the arrival of the slides.
- Follow the implementation of corrective actions and provide technical support to uniformed peripheral laboratories.
- Work in collaboration with RRL if blind rechecking for uniformed peripheral laboratories may be conducted by RRL.
- Store and select positive and negative Blood film slides as indicated in this guideline
- Provide consolidated report quarterly to EPHI

2.2.1.5 Federal hospital Laboratories

- Federal hospital laboratories are not participating in blind rechecking program.

2.2.1.6 Peripheral laboratories

- Store and select positive and negative blood film slides as indicated in this guideline
- Participate in blinded rechecking program organized by the RRLs/sub-regional laboratories/ EQA Sites or Uniformed referral hospitals.
- Take corrective actions and report to RRLs/ sub-regional/EQA centers laboratories or uniformed referral hospitals.

2.2.2 Slide Storage in the Health Facility

- Store all *positive* and *negative* slides in a slide box away from excessive heat and humidity until the slides have been selected.
- Store slides consecutively according to laboratory number so there is a direct link between the results in the laboratory register and the slide location.
- Stored slides should be free from immersion oil. Remove the oil by either gently wiping the film with lens tissue or leaving the slides overnight with the smear side facing down on ordinary tissue paper.

- Slides must have laboratory numbers clearly visible. Slides without laboratory numbers cannot be used for validation purposes.
- Results should not be written on slides; these slides cannot be used for validation purposes.

2.2.3 Sample Size for Rechecking

In accordance with the WHO recommendation, a minimum of 10 slides per month are required for blinded rechecking purpose; 5 *negatives* and 5 *positives*.

2.2.4 Slide Selection and processing Technique

The success of blinded rechecking is critically dependent on correct selection of slide samples. Microscopy slides for rechecking must be selected from the laboratory register and not directly from the slide storage boxes.

2.2.4.1 Systematic Slide Selection Technique

Thirty slides per health facility should be re-examined every three months for accuracy. The following selection technique should be applied during sampling (See also example 1):

- Ten stained malaria slides are selected each month to determine accuracy: 5 *positive* slides and 5 *negative* slides.
- If less than 10 slides are examined in the facility, select all slides for rechecking.
- If the number of *positive* slides examined is less, make up the difference with *negative* slides.
- Ideally malaria slides should be stored for 1 month and the selection made before discarding the slides. The slide selection procedure will be conducted on weekly basis by the laboratory head/quality officer using the procedure described above (select slide from registration book and note the serial number - *put a mark on the register book to identify the selected slides)*.
- During collection of selected slides, the supervisors should counter check the conformity of the selected slides with the laboratory registration book.
- Slides should always be stored for at least 1 week, to allow for patient follow up. If slides are selected weekly, select as follows:

Week 1 - randomly select 2 *positive* slides and 1 *negative* slide
Week 2 - randomly select 1 *positive* slide and 1 *negative* slide
Week 3 - randomly select 1 *positive* slide and 1 *negative* slide
Week 4 - randomly select 1 *positive* slide and 2 *negative* slides

These numbers are the minimum sample size required for statistical analysis (see below). More slides can be selected provided there is sufficient capacity for accurate rechecking of all slides. Either the site supervisor or the facility laboratory personnel should transfer the data of the collected 30 selected slides of each participating health facility laboratory from the laboratory registration book into appropriate form of Annex C.1.

Example 1: Slide selection technique to select 5 negative slides:

1. Count the number of *negative* slides per month; For example the total *negative* slides are 62.
2. Divide by 5 and round up. 62 : 5 = 12.4 = 12 (rounded)
3. Take 12 small pieces of paper and number them 1, 2, 3 . . . 12.
4. Mix them in a container and pick one, for example 3; Start at the 3rd*negative* slide in the register, and select that one. Select every 12th*negative* after that; for example slides 3rd, 15th, 27th, 39th, 51st*negative* slides

   If you do not get enough slides (i.e. either due to loss or broken slide while storing), keep selecting each 12th slide a second time around.

   Follow the same procedure for the *positive* slides. If the five *positive* slides cannot be selected, make up the difference with *negative* slides.

2.2.4.2 Slide processing

- The quality officer or responsible personnel should complete the code number of collected slides in Annex C.2 to provide it to the laboratory personnel (2nd readers) for rechecking and result recording.
- The quality officer or responsible personnel should identify discrepant result(s) and give the discrepant slide(s) and blank form of Annex C.3 to third laboratory personnel in the laboratory. If discrepant result exists between the second and third reader, the two readers will jointly review

the slides and reach consensus. Any slide with unresolved discrepant results should be sent to the higher level laboratory for final decision.

- Give feedback to the testing site with comments and recommendations for appropriate corrective actions using performance notification form (Annex C.4) within a maximum of two weeks' time.
- Send compiled summary report of the participant sites to the higher tier for further analysis and possible quality improvement interventions.

NB:

- *The Regional Laboratories are the higher level laboratories that control the quality services of Sub-regional laboratories, nearby Universities health facility laboratories, and EQA site laboratories.*
- *Laboratories in the private sector (stand alone, medium clinic, higher Clinic, and hospital laboratories) will be provided with similar services by the respective Regional Laboratories or EQA site laboratories designated for the purpose by the Regional Laboratories.*

2.2.5 Result Analysis

Table 4 Result Recording as Positive or Negative on a 2x2 Table Format

		Rechecking labs, Sub-regional and RRLs		
		Positive	*Negative*	*Total*
Source laboratory	*Positive*	A	B	A+B
	Negative	C	D	C+D
	Total	A+C	B+D	*A+B+C+D*

A = number of slides reported as *positive* by both readers *(True positive)*
B = number of slides reported as *positive* in routine testing by the laboratory but found to be *negative* by the cross-checker (false *positives*)
C = number of slides reported as *negative* in routine testing by the laboratory but found to be *positive* by the cross-checker (false *negatives*)
D = number of slides reported as *negative* by both readers *(True negative)*

Results are analyzed as:

1. Percentage of slides in agreement, i.e. percentage of *positive* slides correctly identified and percentage of *negative* slides correctly identified:

$$\% \text{ Agreement} = \frac{\text{True } \textit{positive} + \text{True } \textit{negative}}{\text{Total}} = \frac{(A+D) \times 100}{A+B+C+D}$$

2. False *positive* rate (% false *positives*)

$$\text{False } \textit{positive} \text{ rate} = \frac{\text{False } \textit{positive} \times 100}{\text{True } \textit{positive} + \text{False } \textit{Positive}} = \frac{B \times 100}{A+B}$$

3. False *negative* rate (% false *negatives*)

$$\text{False } \textit{Negative} \text{ Rate} = \frac{\text{False } \textit{Negative} \times 100}{\text{True } \textit{Negative} + \text{False } \textit{Negative}} = \frac{C \times 100}{D+C}$$

Table 5 Example of Result Analysis

		Rechecking labs, Sub-regional and RRLs		
		Positive	*Negative*	*Total*
Source laboratory	*Positive*	A (8)	B (2)	A+B (10)
	Negative	C (1)	D (19)	C+D (20)
	Total	A+C (9)	B+D (21)	*A+B+C+D (30)*

$$\% \text{ Slide Agreement (Detection)} = \frac{\text{True } \textit{positive} + \text{True } \textit{negative}}{\text{Total}} = \frac{(A+D) \times 100\%}{A+B+C+D} = \frac{(8+19) \times 100\%}{30} = 90\%$$

$$\text{False } \textit{positive} \text{ rate} = \frac{\text{False } \textit{positive} \times 100}{\text{True } \textit{positive} + \text{False } \textit{Positive}} = \frac{B \times 100\%}{A+B} = \frac{2 \times 100\%}{10} = 20\%$$

$$\text{False } \textit{Negative} \text{ Rate} = \frac{\text{False } \textit{Negative} \times 100}{\text{True } \textit{Negative} + \text{False } \textit{Negative}} = \frac{C \times 100\%}{D+C} = \frac{1 \times 100\%}{20} = 5\%$$

Table 6 Grading Performance of Slide Rechecking Cycle

Grade	% of slide Agreement (Detection)	Action
Excellent	≥90%	.Congratulate staff for exemplary performance
Very good	80<90%	• Staff should be congratulated for very good performance and told to maintain their performance • Identify any breach for improvement
Good	70<80%	• Staff should be congratulated for good performance and the need for 'further improvement' • Conduct regular on-site Supervision • Check staff competency • Check reagent quality and the microscope • Consider on the job training based on staff's weakness
Poor	≤70%	• Staff should be informed of poor performance and the need for 'immediate action for improvement' • Arrange immediate on-site Supervision. • Check staff competency • Consider intensive on the job training based on staff's weakness • Check reagent quality and the microscope • Regular follow-up for corrective action

NB:

1. *'Error' stand for any positive result reported as negative, or any negative result reported as positive..*
2. *Any EQA performance persistently static or a progressive decreasing pattern in the percentage agreement is an alarming sign that indicates the corrective action has not been effective and should be reviewed immediately.*
3. *Any EQA performance above the previous once is encouraging and still needs follow ups.*

Table 7 Result recording for monitoring the accuracy of the differentiation of *P. falciparum* and non *P. falciparum*

		Rechecking labs, Sub-regional and RRLs		
		P. falciparum Present	*P. falciparum NOT present*	*Total*
Source laboratory	*P. falciparum Present*	A	B	A+B
	P. falciparum NOT present	C	D	C+D
	Total	A+C	B+D	*A+B+C+D*

Where:

A=number of slides reported as containing P.*falciparum* (either as a single or mixed infection) by both readers

B= number of slides reported as containing P.*falciparum* only in routine testing by the laboratory but the presence of P.*falciparum* was not confirmed by the cross-checker (incorrect species identification)

C= number of slides reported as P.*falciparum* not present in routine testing by the laboratory but found to be present by the cross-checker,either as a single or mixed infection (incorrect species identification)

D =number of slides reported as not containing P.*falciparum* by both readers

NB:

1. For specific species, % agreement is calculated from only positive slides reported by the facility
2. species identification % agreement can be calculated for all malaria parasite species including mixed infections

$$\% \text{ Species identification Agreement} = \frac{(A+D)}{A+B+C+D} \times 100\%$$

Table 8 Grading Performance of Species identification

Grade	% of slide Agreement (Detection)	% of Species identification	Action
Excellent	≥90%	≥90%	.Congratulate staff for exemplary performance
Very good	80<90%	80%<90%	• Staff should be congratulated for very good performance and told to maintain their performance • Identify any breach for improvement
Good	70<80%	70%<80%	• Staff should be congratulated for good performance and the need for 'further improvement' • Conduct regular on-site Supervision • Check staff competency • Check reagent quality and the microscope • Consider on the job training based on staff's weakness
Poor	≤70%	≤70%	• Staff should be informed of poor performance and the need for 'immediate action for improvement' • Arrange immediate on-site Supervision. • Check staff competency • Consider intensive on the job training based on staff's weakness • Check reagent quality and the microscope • Regular follow-up for corrective action

2.3 On-site Supervision (for Microscopy and RDT)

On-site supervision of malaria microscopy and RDT requires regular supervisory visits to obtain a realistic picture of laboratory conditions and practices for malaria microscopy and RDT use. On-site supervision includes a comprehensive assessment of laboratory organization, equipment, adequacy and storage of supplies, reagent quality, availability and usage of SOPs, reading and reporting of results and infection control measures using a supervisory checklist. On-site supervision is the ideal way to obtain a realistic assessment of the skills practiced in the testing laboratory/facility, to provide problem solving strategies and corrective action, and assess the need for training. The supervision includes assessment of test performance, provision of on-site training and strengthening of services.

Malaria microscopy on-site supervision is conducted in accordance with NEQAS two times a year by quality officers and malaria experts and others working on malaria quality improvement. Onsite supervision provides an opportunity for basic supervision, including assessment of laboratory supplies storage and inventory, basic procedures, availability of functional equipment, quality of reagents, training status of the laboratory staff, review of laboratory practical skills, work load, safety and waste disposal system, performance of internal QC and result recordkeeping practice. A major advantage of on-site supervision is the ability to identify sources of errors detected by panel testing or rechecking and to implement appropriate measures to resolve problems.

Sufficient time must be allotted for the visit to include observation of all the work associated with malaria microscopy, including preparing films, staining, reading of films by the laboratory personnel and examining a few stained *positive* and *negative* films by supervisors to observe the quality of film preparation and staining as well as condition of microscope.

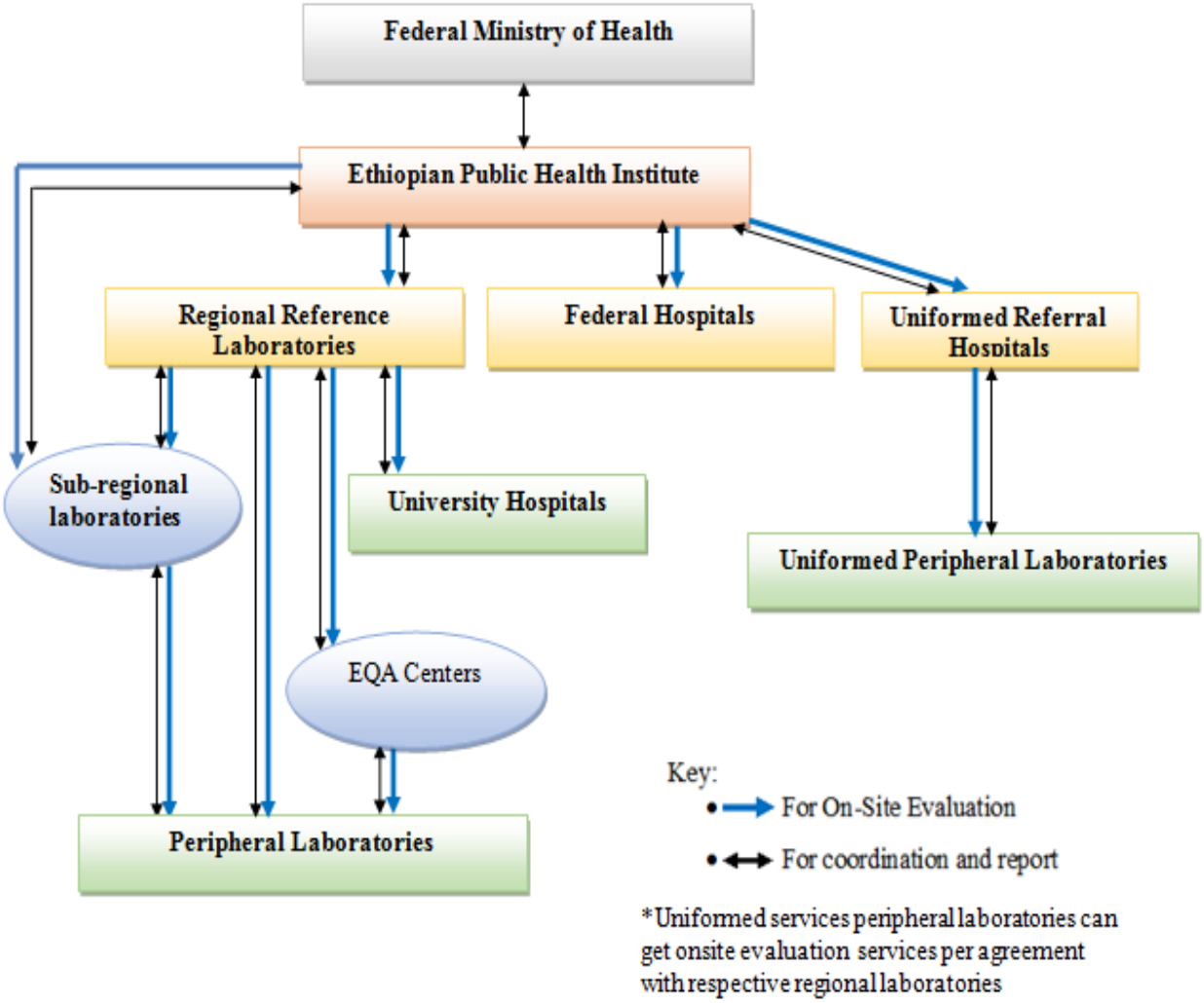


Figure 3: Structure of Onsite Evaluation for Malaria Microscopy

2.3.1 Roles and Responsibilities

2.3.1.1 Ethiopian Public Health Institute

- Set supervision standards; develop/review checklists
- Conduct on-site evaluation to all RRLs, Sub regional laboratories, federal hospitals and Uniformed services (Army, Federal Police and Federal Prison hospital laboratories) based on their PT performance.
- Conduct on-site evaluation for any health facility to evaluate the overall program as needed.

- Send feedback on time to RRLs, RRLs, Sub regional laboratories, federal hospitals and Uniformed services, RHB and other authorized bodies within two weeks of data arrival at EPHI
- Follow the implementation of corrective actions and provide training and technical support
- Prepare report on the performance of laboratories based on on-site evaluation to the national laboratory technical working group when found necessary.
- Provide consolidated bi-annually summary report to FMOH
- Organize review meetings annually.

2.3.1.2 Regional Reference Laboratories

- Participate in on-site evaluation conducted by EPHI
- Take corrective actions for the identified gaps and report to EPHI within two weeks.
- Conduct on-site evaluation for, university hospitals, EQA centers and sub-regional laboratories.
- Conduct on-site evaluation to laboratories which are not covered by sub-regional and EQA center laboratories.
- Conduct on-site evaluation for uniformed peripheral laboratories if requested a support by uniformed services.
- Conduct on-site evaluation for any health facility in their respective region to evaluate the overall program as needed.
- Send feedback to participant laboratories within two weeks of data arrival at regional laboratory
- Follow the implementation of corrective actions and provide training and technical support to participant laboratories.
- Provide consolidated bi-annually summary report to RHB and EPHI
- Provide timely data and documentation to facilitate on-site supervision by EPHI
- Organize review meetings annually.

2.3.1.3 Sub Regional Laboratories and EQA centers

- Participate in on-site evaluation conducted by RRLs and EPHI(for Sub regional laboratories only)

- Take corrective actions for the identified gaps and report to RRLs/EPHI within two weeks
- Conduct on-site evaluation to peripheral laboratories.
- Send feedback to participant laboratories within two weeks of data arrival at the EQA sites and sub-regional laboratories.
- Follow the implementation of corrective actions and provide training and technical support to participant laboratories.
- Provide consolidated bi-annually summary report to RRLs

2.3.1.4 Uniformed services (Army, Federal Police and Federal Prison hospital laboratories)

- Participate in on-site evaluation conducted by EPHI
- Take corrective actions and report to EPHI.
- Conduct on-site evaluation to uniformed peripheral laboratories.
- Send feedback to participant laboratories within two weeks of data arrival
- Follow the implementation of corrective actions and provide training and technical support to participant laboratories.
- Work in collaboration with RRL if on-site evaluation for uniformed peripheral laboratories may be conducted by RRL.
- Provide consolidated bi-annually summary report to EPHI

2.3.1.5 Federal hospital Laboratories

- Participate on on-site evaluation conducted by EPHI
- Take corrective actions for the identified gaps and report to EPHI
- Provide all the necessary data and documents to EPHI to facilitate on-site supervision

2.3.1.6 Peripheral laboratories

- Participate in on-site evaluation conducted by RRLs/EQA sites/Uniformed services/sub-regional Laboratories
- Take corrective actions for the identified gaps and report to RRLs/EQA sites/Uniformed services/sub-regional Laboratories within two weeks.

- Provide all the necessary data and documents to facilitate on-site supervision by RRLs/EQA sites/Uniformed services/sub-regional Laboratories

2.3.1.7 Health Posts

- Health Posts are responsible for provision of malaria laboratory diagnosis using RDTs.
- Health posts are expected to implement basic QA activities for malaria diagnosis and must be involved in REQAS through onsite supervision by the higher tier laboratory.
- Health posts are expected to implement standard supply chain management systems for RDTs.

2.3.2 On-site Supervision for Malaria RDT

On-site supervision for malaria RDT should be performed two times a year by HEWs Supervisor (HEWS) and others working on malaria RDT quality improvement. On-site supervision provides an opportunity for assessment of RDT supplies storage conditions, inventory, and basic procedures of RDT including sample collection, skill of HEW to perform RDTs, internal quality control, result interpretation, recording and reporting, safety practice and waste disposal, and need of retraining by using a supervisory checklist (Annex D.3). A major advantage of on-site supervision is the ability to identify sources of errors and provide on-site corrective actions to improve the quality of test results and implement appropriate measures to resolve problems.

2.3.2.1 Supervisory checklist

Every EQA scheme will need to have checklists to assist laboratory supervisors during the on-site visits and standardize collection and analysis of data for subsequent remedial action. Checklists may be revised in the light of problems that are identified during such visits.

A comprehensive list of all operational elements to be observed will help to ensure consistency in laboratory evaluations and provision of immediate feedback to facilitate rapid corrective action. It also serves as means of documentation of the visit and a record of current conditions and actions needed. The checklist should be completed during the visit and discussed with the test performer before the supervisor leaves the health facility. Filled checklists should be submitted to the onsite supervision organizer after completion of each visit.

Feedback containing need for corrective action or additional resources should be reported to each respective health facility through the recommended channel of communication and a consolidated summary report need to be submitted to EPHI and Regional Health Bureaus.

Supervisory checklists for on-site supervision of malaria diagnosis (microscopy and RDT) are provided in Annexes D.2 and D.3. These checklists contain open, non-leading questions and recommended observations along with objective criteria for acceptable practices. By using open, non-leading questions, as well as direct observation of daily practices, the supervisor can assess how well the laboratory personnel understand proper procedures, and is not just providing the expected "yes" response. These detailed checklists provide a template that may be adapted to meet the specific needs of EQA at each level. The preferred format should include simple, objective "Yes/No" evaluation criteria, yielding data that can easily be entered into a database for long term tracking and comparing performance.

Documentation of any significant problems requires development of strategies and activities for improvement of quality.

2.3.2.2 General Activities to be considered for On-site Supervision

- Make a schedule for site visits.
- Form a supervisory team.
- Prepare necessary materials like the check list and feedback report.
- Arrange logistics for the site visit.
- Conduct on-site supervision.
- Review the previous site supervision feedback (if available).
- Provide EQA feedback, investigate any poor performances, and make corrective action and follow-up.

NB: *SOP for on-site supervision is explained in Annex D.1.*

2.3.2.3 Resource Requirements for On-site Supervision:

- Logistics (vehicles and per diem).
- Supervisors.
- Standard Checklist.
- Format for immediate feedback.

- Fax, e-mail and web based services for communication.

2.3.3 Procedure for Malaria Microscopy On-site Supervision

Tasks to be done by supervisory team:

- EPHI and Regional Laboratories are coordinating bodies for malaria laboratory diagnosis EQA in their respective operational setting.
- For EQA activity by EPHI, the National Quality Officers arrange the logistics including checklists, and select the supervisory team members one month prior to the starting day of the on-site supervisory visit by communicating with the National Quality Manager.
- For EQA activities at regional, sub-regional and EQA sites, Quality Officers at each level arrange the logistics including checklists, and select the supervisory team members one month prior to the starting day of the on-site supervisory visit.
- The respective Quality Officers inform selected supervisors 15 days prior to the starting date of onsite supervision and identify team leaders of each supervisory team.
- The respective Quality Officers arrange orientation session for the supervisory team, prepare official letters for each supervisory team and communicate with the participating health facility one week before the starting date of the onsite supervision.
- The supervisory teams participate in the orientation session a day before the starting date of onsite supervision and collect the checklist and other items needed for the onsite visit.
- At the health facility level, the supervisors follow the SOP to Conduct On-site Supervision (see Annex-D.1).
- The team leaders of each supervisory team submit the completed checklist to the respective Quality Officers after completing the onsite supervision.
- The National and Regional, sub-regional and EQA sites Quality Officers prepare feedback and corrective action needed for each participating laboratory within a 15 days after the visit and also compile summary reports all participant sites, and report to the EPHI and Regional Health Bureaus.
-

- The respective Quality Officers develop site specific corrective action plan to address the identified gaps, and lead its implementation to strengthen the malaria diagnosis services based on the recommendations stated in the report.
- The respective Quality Officers follow the implementation of the feedback/corrective actions given.

2.3.4 Procedure for Malaria RDT On-site Supervision

- Regional Laboratories are the coordinating bodies for malaria RDT EQA in their respective operational setting.
- In consultation with Regional Laboratories, Zonal laboratory experts and/or Zonal malaria experts provide technical and logistical support for HEWS and others working on malaria RDT quality improvement including provision of orientation sessions prior to the initiation of the onsite supervision activity.
- All HEWSs need to participate in the orientation sessions before performing onsite evaluation and need to collect the relevant checklists and formats.
- At the health posts, the HEWSs need to follow the standard SOP to Conduct On-site Supervision (See annex-D.1).
- The HEWS submits a copy of the completed checklist to the Zonal laboratory expert and/or Zonal malaria expert after completing the onsite supervision within two weeks of the visit.
- The HEWS is also expected to prepare and give feedback and takes corrective action for each participating site within 15 days of the visit.
- The Zonal laboratory expert and/or Zonal malaria expert sends a compiled summary report of each participant sites to the RRL, Zonal Health Departments and Regional Health Bureaus.
- Based on the recommendations and corrective action stated in the report the Regional Laboratory, Zonal Health Department, District Health Office and the HEWS plan to take corrective actions for the major gaps identified and continue to strengthen the malaria RDT services.
- The Regional Laboratory, sub regional laboratory and EQA sites provides a summarized report of findings from onsite supervision to the National Quality Manager every six months.

3 ANNEXES

Annex-A Participant Laboratory Registration Form for Panel Testing

Region_____

City/Town_____

Facility name_____

Office phone_____

Fax_____

Address of 1st Contact

- Name_____
- Job Title_____
- Mobile_____
- Fax_____
- E-mail_____

Address of 2nd Contact

- Name_____
- Job Title_____
- Mobile_____
- Fax_____
- E-mail_____

You may Contact

P. O. Box 1242/5654 Tel: +251 11-2751522/2753470 +251 11- 2754744 E-mail: EPHI@ethionet.et

Annex-B Instruction, Result Reporting and Feedback Form for Malaria Microscopy Panel Testing

B.1. Instructions for Reading Malaria Slide Panel Testing

1. Before proceeding to reading the slide, read the instructions and all forms carefully
2. Make sure that the panel contains 10 slides and are properly labeled.
3. Read all the ten panel slides as if you examined routine clinical blood film samples.
4. Heath facility level laboratory staff who routinely reads malaria slides of patients is expected to read and report the reading of panel slides in a similar way.
5. Laboratories are expected to properly handle and return the panel slides.
6. Record your finding appropriately.
7. Submit the completed result form to the responsible body using fax, e-mail or post with a contact address of the respective institutions.

Caution

- Panel slides should be treated as if potentially infectious.

B.2. Result Reporting Form at the Health Facility for Reading Malaria Slide Panel Testing

Region _____

Zone_____

Woreda_____

Name of health facility/ laboratory _____

Date received by the health facility laboratory _____Received by_____

Slide ID	*Negative*	*Positive*			Remark
		Species	Stage	Parasite Load	

Date read: _____ Date reported_____

Name and signature of the reader:_____

B.3. Feedback Reporting Form for Reading Malaria Slide Panel Testing

Region _____

Name of health facility/ laboratory _____

Date feedback reported_____

Slide ID	Species		Stage of parasite		Parasite Load		Remark
	Result expected	Result reported	Result expected	Result reported	Result expected	Result reported	

Total score and grade of the laboratory: _____
Recommended actions for improvement:

1._____3._____

2._____4._____

Keys

Result Expected: the correct result according to the reference reader.

Result Reported: the score of audited laboratory (correct or incorrect).

Name and signature of authorized person: _____

Annex C. Blinded rechecking result recording and feedback forms

C.1. Selected Slide Result Recording Form for Rechecking

Region _____Zone_____Woreda_____ _____Health Facility _____

Date sent to Rechecking Laboratory_____Total No. of slides _____

Date received at Rechecking Laboratory_____Total No. of slides received_____

Name and Initial of Receiver at Rechecking Laboratory_____

Slide ID.	Diagnostic Result at the Health Facility from Laboratory Registration Book (1st Reader)						Parasite Density	Remark
	Neg.	*Positive*				Stage of Malaria Parasite (for *positive* Slide)		
		PV	PF	Mixed	Others			
Total								

Name and signature of laboratory personnel _____

Date _____

C.2. Slide Reader Result Record Form for Rechecking (2nd Reader)

Rechecking Laboratory_____

Region _____Zone_____Woreda_____ Health Facility_____

Total slides Received_____ Source_____

Name of laboratory personnel, who examine the slides _____

Slide ID	2nd Reader result (At the Rechecking Lab.)						Parasite Density	Slide quality grading			Remark
	Neg.	*Positive*				Stage (for *positive* Slide)		Excellent	Good	Poor	
		PV	PF	Mixed	Others						
Total											

NB: -Quality of blood film includes size and thickness of the film and quality of the staining.

Key for Slide quality grading

Excellent

Gross appearance: Both thin and thick film prepared on the same slide, thick film 10 mm diameter, newsprint read under thick film before staining, 10 mm from frosted end and thick film, 10 mm between thick and a thin film with distinct head, body and tail.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Good

Gross appearance: Thick film with irregular and uneven thickness, thin film with uneven tail, too thick, too wide or too long.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Poor

Gross appearance: Film with ragged tail, too thick, too wide or too long with uneven thickness.

Microscopic appearance: Distorted appearance of the RBCs, malaria parasite and the white cells. Difficult to spot fields with monolayer of cells on thin film, lack of white blood cells to be clearly distinguished against the background and no properly lysed RBCs in thick film.

Name of 2nd reader_____Signature_____ Date_____

General comment _____

_____

C.3. Slide Reader Result Record Form for Rechecking (3rd Reader for Discordant Result)

Rechecking Laboratory_____

Region _____Zone_____Woreda_____ Health Facility_____

Total slides Received_____ Source_____

Name of laboratory personnel, who examine the slides _____

Slide ID	3rd Reader result (At the Rechecking Lab.)						Parasite Density	Slide quality grading			Remark
	Neg.	*Positive*				Stage (for *positive* Slide)		Excellent	Good	Poor	
		PV	PF	Mixed	Others						
Total											

NB: -Quality of blood film includes size and thickness of the film and quality of the staining.

Key for Slide quality grading

Excellent

Gross appearance: Both thin and thick film prepared on the same slide, thick film 10 mm diameter, newsprint read under thick film before staining, 10 mm from frosted end and thick film, 10 mm between thick and a thin film with distinct head, body and tail.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Good

Gross appearance: Thick film with irregular and uneven thickness, thin film with uneven tail, too thick, too wide or too long.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Poor

Gross appearance: Film with ragged tail, too thick, too wide or too long with uneven thickness.

Microscopic appearance: Distorted appearance of the RBCs, malaria parasite and the white cells. Difficult to spot fields with monolayer of cells on thin film, lack of white blood cells to be clearly distinguished against the background and no properly lysed RBCs in thick film.

Name of 3rd reader_____Signature_____ Date_____

General comment _____

_____

C.4. Performance Notification Form

Notification No: _____
Code No. _____

To: _____

From: _____

I. Total No. of slides with correct reading ☐	IV. Grading of performance by % of Agreement • Excellent (≥90%) ☐ • Very good (80-90% ☐ • Good (70-80%) ☐ • Poor (≤70%) ☐ • % of false *positive* ☐ • % of false *negative* ☐
II. Total number of slide with discordant results ☐	
III. Type of discordance: • # Positive diagnosed as negative ☐ • # Negative diagnosed as positive ☐ • # Species misdiagnosis ☐	

III) Recommendation

General_____
_____

Specific_____
_____

Feedback Summary Table

Slide ID.	Result				Slide Quality		Remark
	Correctly read	Discordant			Good	Poor	
		Pos. Report as Neg.	Neg. Report as Pos.	Species Misdiagnosed			
Total							

Key for Slide quality grading

Excellent

Gross appearance: Both thin and thick film prepared on the same slide, thick film 10 mm diameter, newsprint read under thick film before staining, 10 mm from frosted end and thick film, 10 mm between thick and a thin film with distinct head, body and tail.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Good

Gross appearance: Thick film with irregular and uneven thickness, thin film with uneven tail, too thick, too wide or too long.

Microscopic appearance: Demonstrates RBCs lysed in thick film and a monolayer of RBCs, with normal and abnormal morphology in thin film. Staining allows the trophozoites, gametocytes and/or schizonts and the white blood cells to be clearly distinguished against the background.

Poor

Gross appearance: Film with ragged tail, too thick, too wide or too long with uneven thickness.

Microscopic appearance: Distorted appearance of the RBCs, malaria parasite and the white cells. Difficult to spot fields with monolayer of cells on thin film, lack of white blood cells to be clearly distinguished against the background and no properly lysed RBCs in thick film.

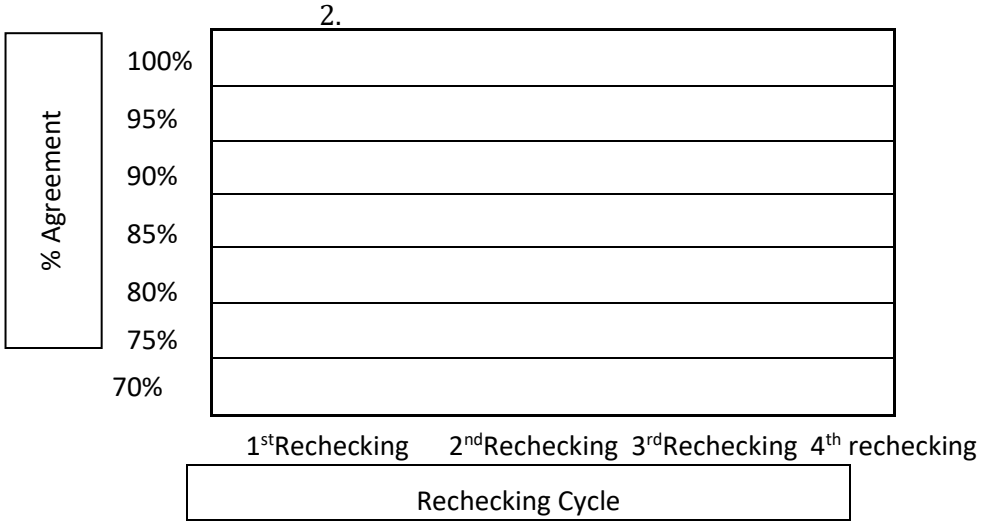
Name and signature of authorized personnel:_____

Date: _____

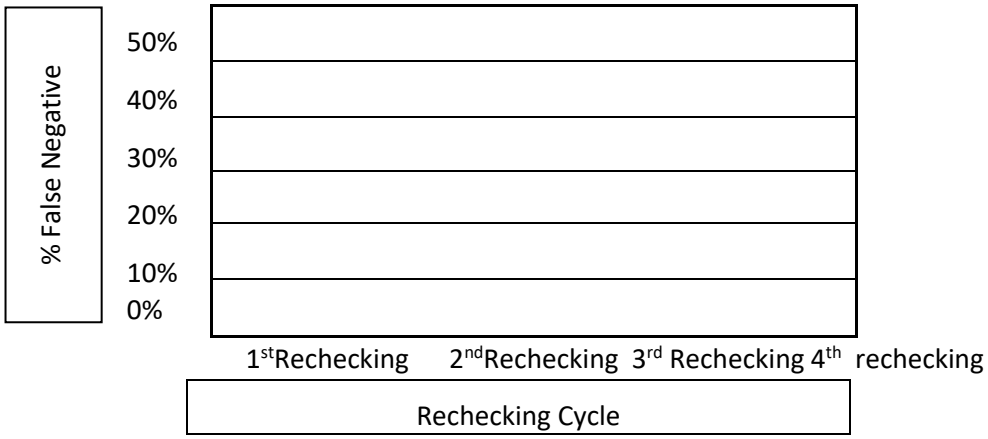
C.5. Annual Feedback Form for Participant Health Facility in Blinded Rechecking

1. **% Agreement in the four consecutive rechecking scheme**

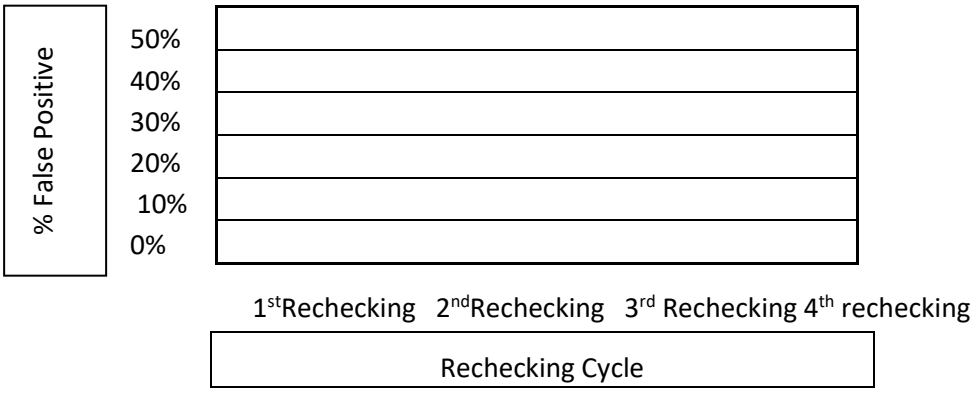
2.



2. % False Negative in the four consecutive slide rechecking cycle



3. %False *Positive* in the four consecutive slide rechecking cycle



Annex D. SOPs and checklist to Conduct On-site Supervision

D.1. SOP to Conduct On-site Supervision

Purpose:

- To assess site performance and compliance with quality assurance implementation.
- To provide on-site supervision and support.
- To monitor process improvement.
- To gather data.

Scope:

- To be used for guiding onsite supervision of malaria diagnosis at Health facility level by national, regional, sub regional, EQA sites, zonal and facility level supervisors.

Materials required:

- A new checklist (for general laboratory).
- Previous checklist (if available).
- EQA reports.

Procedure:

- Introduce yourself to the laboratory head (HEW at Health Post) and state the purpose of your visit.
- Ask the laboratory head (HEW at Health Post) if you could meet have brief meeting with him/her as well as the quality officer in private.
- Encourage the laboratory head and quality officer (HEW at Health Post) to feel comfortable. Spend a little time making general enquiries into the overall health facility laboratory (Health Post) activities.
- Discuss the previous site visit; check if the action items are completed and implemented.

- Ask the health facility laboratory head (HEW at Health Post) the questions on the checklist and write down the scores.
- Discuss EQA report feedback, investigate any poor performances. Check if corrective actions have been implemented. If not, ask for reasons or constraints to implementing corrective actions, arrange to provide necessary support, and agree on corrective actions to be implemented and followed up.
- Ask the health facility laboratory head (HEW at Health Post) to show you the laboratory (Health Post). During this time, pay special attention to observing the following:
    - Effective and efficient work flow
    - Staff competency
    - Use of SOPs
    - Equipment maintenance and completed records
    - Use of quality controls and completed records
    - Complete correction logs
    - Inventory system
    - Adherence to safety
    - Adequate infrastructure

This is an opportunity to ensure the questionnaire answers match the reality in the laboratory, as well as to provide on-site supervision.

- Ensure the checklist is complete and scores added correctly.
- Conduct an exit interview with the manager. Provide praise where appropriate. Discuss challenging areas and non-compliance, and make recommendations.
- If there are critical problems in the laboratory, discuss these with the laboratory head and agree on actions for immediate implementation (such cases should be reported to the national laboratory quality manager for follow up).
- It is important to build good relations with the laboratory head and staff. The visit should be positive, encouraging and supportive.

Total time of site visit will vary per laboratory. However, a supervisory visit for minimum of **6hours** is recommended.

Outcomes and follow up:

- The supervisor will review the supervision result and send reports back to the sites within 15 days.
- The report will include recommendations for process improvement, and laboratory heads (HEWs) are expected to implement such activities.
- All activities will be followed up during the next site visit.
- Where health facility laboratories (Health Posts) have poor performance, arrangements will be made by the quality officers (HEWS) for the provision of intensive on-site mentorship.
- Where laboratories perform poorly and do not comply with recommendations, a letter of non-compliance will be sent to the laboratory and hospital medical officer (Woreda Health Office).
- Wherever necessary, the NRL/RRL will provide assistance and support.
- The National Quality Manager and Regional Quality Officer will compile an annual summary report and submit it to the EPHI and Regional Health Bureau, respectively.

D.2. Supervisory Checklist for Malaria Microscopy Laboratory Service

Region_____ Zone_____ Woreda_____

Name of health facility _____

Name of laboratory department head_____

Tel. No_____ Fax_____

Date of onsite supervision conducted_____

I. Training

No	Questions	Responses				
	Total No. Of lab staff___ Number of laboratory personnel trained on malaria microscopy___	Name of trained staff in the fiscal year	When was s/he trained? (mm/yyyy EC)	How long was the training? (# of Days)	Who provided the training? (Organization)	Comments
	Comments					

II. Malaria microscopy laboratory format and supplies

	Are the following malaria microscopy formats and other materials available?	Items	1 = Available and being used 2 = Available, but not used 3 = Not Available
		Malaria microscopy guideline	
		SOP for malaria microscopy	
		Laboratory result log book	
		Job aids	
		Weakly /monthly report form for malaria	

	Are the following reagents and other	Item	1 = Available and being used	Enough for the
	Laboratory commodities available?		2 = Available, but not used 3= Not Available 4= Not Applicable	coming 4 Months 1= Yes 2=No
		Absolute methanol		
		Absorbent cotton wool		
		Beaker/volumetric flask		
		Binocular microscope with electric source of light		
		Brown bottle		
		Distilled water		
		Drying rack		
		Funnel		
		Giemsa powder/Giemsa stain stock solution		
		Glass beads		
		Glycerol		
		Immersion oil		
		Timer		
		Lens cleaning solution		
		Lens paper		
		Measuring cylinder		
		Microscope slides		
		Glass-writing pen/lead pencil		
		Slide boxes		
		Staining rack		
		Staining jar		
		Tally counter		
		Tissue paper		

	Reagents labeled with its name, date of preparation and expiry date (observation)	1-Yes 2- No

III. Equipment

	How many electric binocular microscopes do you have?	Brand name (*for the first EQA cycle but for other cycle fill this column if there is New arrival*)	# Functional	# Non Functional	Specific problem (examine stained blood film slide to fill this column)	Remark
		Total				

IV. Malaria microscopy skill assessment

	Who is responsible for sample collection?	1. Laboratory personnel 2. Non laboratory personnel 3. If non laboratory personnel, specify _____	☐ ☐ ☐
	Which type of blood film do you use for malaria diagnosis?	1. Always thin smear 2. Always thick smear 3. As necessary 4. Always both (in the same slide or separate slide)	☐ ☐ ☐ ☐
	Quality of thick and thin films? (observation)	1. Excellent 2. Good 3. Poor	☐ ☐ ☐
	How do you dry the film?	1. Air dry 2. Heat dry	☐ ☐

	Which part of the film (thin or thick) do you fix?	1. Thin 2. Thick 3. Both	☐ ☐ ☐
	How many fields do you examine to report a *negative* result (no parasites)?	1. <25 2. 50 3. 100 4. 200 5. _____	☐ ☐ ☐ ☐ ☐
	Do you report *positive* results by identifying species and parasite stages?	1. Species only 2. Stages only 3. Both 4. None	☐ ☐ ☐ ☐
	Do you quantify *positive* results (parasite density)?	1. Yes 2. No 3. if Yes, which method specify _____	☐ ☐
	When using WBC method, how many WBC do you count to quantify a parasite load?	1. 50 WBC 2. 100 WBC 3. 200 WBC 4. 500 WBC 5. Not applicable	☐ ☐ ☐ ☐ ☐
	Do you clean the microscope or objective lenses prior to starting microscope reading and at the end of the day?	1. Yes 2. No	☐ ☐
	What do you use for microscope lens cleaning?	1. Cotton 2. Lens paper 3. Tissue paper 4. Other _____	☐ ☐ ☐ ☐
	Which reagent do you use for blood film staining?	1. Giemsa 2. Wright 3. If other, specify_____?	☐ ☐ ☐
	For Giemsa stain		

	Do you prepare the stock reagent or use ready-made reagent?	1. Preparing reagent 2. Readymade reagent	☐ ☐
	How often do you prepare the working reagent?	1. Every 24 hrs 2. Prior to staining 3. Other specify_____	☐ ☐ ☐
	What is the commonly used reagent container to store the stock stain?	1. Brown bottle 2. Any transparent bottle	☐ ☐ ☐
		3. If other, specify _____	
	Where do you store the stock reagent?	1. Away from direct sunlight and moisture in lockable cabinet 2. Other, specify_____	☐ ☐
	Have you ever interrupted malaria laboratory services due to shortages of reagents, supplies and microscope problem?	1. Yes 2. No If yes 1. Cause of interruption_____ 2. For how long _____ 3. How many times in the last 4 months _____	☐ ☐ ☐ ☐ ☐
	Have you experienced some difficulties with your microscope during the last 4 months?	1=y es 2= No If y es, 1. with the Stage with 2. the objective 3. other specify,_____	☐ ☐ ☐ ☐ ☐
	Do you have an inventory list of supplies and stains?	1. Yes 2. No	☐ ☐
	How often do you receive supplies like stains and others?	1. Monthly 2. Every 6 months 3. Once a year	☐ ☐ ☐

	Do you have difficulties receiving your supplies?	1. Yes 2. No 3. If yes, why _____	☐ ☐ ☐
	Do you store patient blood (with EDTA) known to have parasites	1. Yes 2. No	☐ ☐
	Do you keep slides for rechecking?	1. Yes 2. No 3. If no why? _____	☐ ☐ ☐
	Have you been supervised in the past 6 months?	1. Yes 2. No 3. If yes specify the supervisor _____	☐ ☐ ☐
	Is a standard laboratory register book in use?	1. Yes 2. No 3. If not why? _____	☐ ☐ ☐
	Is a standard laboratory request form in use?	1. Yes 2. No 3. If not why? _____	☐ ☐ ☐

V. Quality Assurance

	Internal Quality Control (QC) Practiced		
	Do you prepare *positive* and *negative* slides for reagent quality control purposes?	1. Yes 2. No, if no why? _____	☐ ☐
	When do you conduct internal quality control for malaria microscopy?	1. Weekly 2. Monthly 3. Upon opening of new batch_ 4. During unusual staining results 5. Others, Specify _____	☐ ☐
	Are stained slides ever rechecked by a person in the laboratory?	1. Yes 2. No, if no why? _____	☐ ☐

	EQA practiced		
	Are stained slides validated regularly, and feedback obtained?	1. Yes 2. No, if no why? _____	☐ ☐
	Do you participate in an EQA scheme, and is feedback obtained	1. Yes 2. No, if no why? _____	☐ ☐

VI. Safety and waste Disposal

	Are gloves and gowns worn while performing the procedure?	1. Yes 2. No, if no why? _____	☐ ☐
	Are a safety box/sharp container and non-sharp container available and placed in the right position?	1. Yes 2. No, if no why? _____	☐ ☐
	Is the working area clean and decontaminated before/after procedures?	1. Yes 2. No, if no why? _____	☐ ☐
	Is waste disposed of in the appropriate container (sharp material to sharp container and non-sharps to non-sharp container)?	1. 2. Yes No, if no why? _____	☐ ☐

3. How many blood film slides have been examined during the last four months?

Year	***Positive***					***Negative***	**Total**
	Malaria				**Other**		
	Pf	*Pv*	Mixed *Pf and Pv*	Others	**Hemoparasit**e (specify)		

4. **SUPERVISORS' COMMENTS (best practices, major problems identified, suggested solutions) on MALARIA MICROSCOPY**

BEST PRACTICES:

_____

_____

_____

MAJOR PROBLEM IDENTIFIED:

_____

_____

_____

SUGGESTED SOLUTIONS: _

_____

_____

_____

SUPERVISORS

NAMESIGNATURE

1._____ _____

2._____ _____

3._____ _____

D.3. Supervisory Checklist for Malaria RDT Service

Region_____ Zone_____ Woreda_____

Name of Health Post supervised_____

Name responsible staff_____ Tel.

No/Fax/P.O.Box_____

Date of onsite supervision conducted_____

I. Training

No	Questions	Responses				
	Total No. of staff___ Number of staff trained on RDT____	Name of trained staff in the fiscal year	When was s/he trained? (mm/yyyy EC)	How long was the training? (# of Days)	Who (the organization) Provided the training?	Comments
	Comments					

II. Document and supplies

	Are the following malaria RDT documents available?	**Items**	**1 = Available and being used** **2 = Available, but not used** **3 = Not Available**
		Malaria RDT guideline	
		SOP for malaria RDT	

		Malaria RDT log book		
		Malaria RDT job aid		
		Weekly/monthly report form		
	Are the following RDT Kits and consumables available?	**Items**	**1 = Available and being used** **2 = Available, but not used** **3= Not available**	**Enough for the coming 4 months 1= Yes** **2=No**
		Multi species RDT kit		
		Single species RDT kit		
		Sterile blood lancet		
		Timer		
		Absorbent cotton wool		
		Labeling pen/pencil		
		70% Ethanol		

III. Malaria RDT Skill Assessment, Storage and Inventory

	Observe the actual sample collection procedure • Collect the necessary items before blood collection • Disinfect the finger before pricking • Wipe away the first drop • Collect adequate volume of blood	1. Adheres to the test procedure 2. Doesn't adhere to the test procedure 3. If not , list problem identified _____ _____	☐ ☐ ☐

	Observe the actual test performing procedure. • Reads expiry date before opening the kit • Dispenses correct volume of blood	1. Adheres to the test procedure 2. Does not adhere to the test procedure 3. If not, list problem identified _____	☐ ☐ ☐
	to proper well • Keeps exact time of result reading • Correctly interprets the result • Correctly records the result	_____	
	Whom do you consult if you encounter a problem with RDT performance?	1. HEW supervisor 2. Zonal malaria expert 3. Other, specify_____	☐ ☐ ☐
	How often do you receive supplies like RDT kits and consumables?	1. Monthly 2. Every 6 months 3. Once a year 4. Other, specify_____	☐ ☐ ☐ ☐
	Do you have difficulties receiving your supplies?	1. Yes 2. No 3. If yes, why _____	☐ ☐ ☐
	Do you check the expiry date of the RDT before performing the test?	1. Yes 2. No	☐ ☐
	Do you store RDT kits according to the manufacturer's instructions?	1. Yes 2. No, if no why? _____	☐ ☐
	Do you have an inventory system to control stock outs of RDTs and consumables?	1. Yes 2. No, if no why? _____	☐ ☐
	Have you ever been supervised during the past four months?	1. Yes 2. No 3. If yes, specify the supervisor _____	☐ ☐ ☐

IV. Safety and waste disposal

	Gloves and gowns worn while performing RDTs	1. Yes 2. No, if no why? _____	☐ ☐
	Safety box/sharps container and nonsharps container available and placed in the right position?	1. Yes 2. No, if no why? _____	☐ ☐
	Working area clean and decontaminated before/after test procedure?	1. Yes 2. No, if no why? _____	☐ ☐
	Waste disposed of in the appropriate container (sharps material to sharps container and non-sharps to non-sharps container).	1. 2. Yes No, if no why? _____	☐ ☐

3. **How many RDT have been performed during the last four months?**

Year	*Positive*			*Negative*	Total
	Pf	*Pv*	Others		

4. **SUPERVISORS' COMMENTS (best practices, major problems identified, suggested solutions) on MALARIA RDT**

BEST PRACTICE :

_____

_____

_____

_____

_____

MAJOR PROBLEM IDENTIFIED:

_____

_____

_____

_____
_____

SUGGESTED SOLUTIONS:

_____

_____
_____

_____
_____

SUPERVISORS

NAMESIGNATURE

1._____ _____

2._____ _____

3. _____ _____

Annex E. Trouble Shooting for Malaria Microscopy Examination

Misdiagnosis		
Possible causes	**Notes**	**Suggested actions**
• Very low parasite density	• Very low parasite density may cause false *negative* results unless 100 fields are examined before reporting as *negative*. • Because low parasite densities can be difficult to detect on occasions it is correct for a clinician to request a reexamination in some cases.	• The laboratory staff should read at least 100 fields. • Consider retraining of the Laboratory staff.
• Low skill level by the laboratory staff	• Low laboratory staff competency. • Lack of refresher training. • Low laboratory staff motivation.	• Consider retraining of the Laboratory staff. • Proper mentorship of the laboratory staff.
• Pressure on laboratory staff by clinical staff to find malaria parasites when there is a clinical suspicion of malaria.	• Some clinical staff can be critical of laboratories (and assume poor quality slide examination) that report negative findings in patients with symptoms consistent with malaria.	• The clinical staff should be fully aware of the laboratory QC results – if the QC results are good then the clinical staff should trust the results of the laboratory.
• Laboratory staff choosing to report negative slides as 'weakly positive' because they believe this is 'safer'.	• A major problem that can be caused by either (1) lack of skill or confidence; (2) pressure from clinicians; (3) substandard equipment, e.g. sub-quality microscope and reagents, lack of electrical supply.	• Laboratory staff retraining to increase their skill and confidence. • Discuss with the clinical staff regarding the laboratory diagnostic procedure and the patient's condition. • Ensure quality of microscope and reagents, and access to a power supply.

• Artifacts such as stain deposit • (Precipitation of Giemsa stain solution) may be incorrectly interpreted as malaria parasites.	• Staining with dilute Giemsa stain older than 24hrs after preparation; using poorly cleaned slides; fungus contaminated slides; non filtered Giemsa working solution and shaking the stock Giemsa solution immediately before dilution.	• Prepare diluted Giemsa stain immediately and filter before use. • Use only new slides or slides that have been fully cleaned. • Never use slides that have become contaminated by fungus. • Retrain staff in good laboratory technique and recognition of artifacts.
• Howell-Jolly bodies	• Caused by poor laboratory reading skill;	• Retrain laboratory staff.
• and Platelets misidentified as malaria parasites	• Platelets are less of a problem as laboratory staff is familiar with their morphology; laboratory staff can be less familiar with Heinz bodies.	•
• High workload causing the laboratory personnel to examine slides too quickly.	• The maximum workload capacity of laboratory personnel should not be exceeded. It is also important to note that malaria slides are often examined by a laboratory during a peak period during the day rather than evenly distributed over the whole day. The laboratory workload capacity needs to be particularly managed during these peak workload periods.	• Improve facility workload management.
• Poor quality thick and thin blood films preparation	• Technical incompetency of laboratory personnel	• Retrain laboratory staff
• Poor quality microscope(s)	• The sensitivity of malaria microscopy is directly dependent upon the quality of the microscope, and the quality of the illumination. In particular using a mirror microscope on a cloudy day will significantly reduce sensitivity.	• Upgrade the microscope(s) and provide electrical illumination.
• Poor quality stains	• For maximum sensitivity malaria parasites should be identified by a combination of morphology and color. This requires a good quality stain and correct staining technique.	• Purchase only high quality stains.
• Poor staining technique	• Assuming a good quality stain is used, then poor staining can be attributed to staining technique.	• Retrain laboratory staff in staining methodology.

Annex F. Quality Indicators for Malaria Laboratory Diagnosis

F.1. Quality Indicators for Malaria Microscopy

- **SOPs** and **job and bench aids** for malaria microscopy diagnosis are in place.
- **Qualified staff**
    - Trained laboratory personnel on malaria microscopy

  Functional equipment
    - Microscope in good working order
    - Availability of maintenance and cleaning records
    - Functional timer and tally counter

  Reagent preparation and storage
    - Fresh working reagent from stock solution are used daily
    - Reagent stored according to the manufacturer instructions (Giemsa stain should be stored in brown bottle)
    - Clearly labeled reagent

  Quality control
    - Every new batch reagents regularly checked using known positive and negative blood films and documented
- **EQA (External Quality Assessment)**
    - EQA participation and documentation
    - Mechanisms or process for implementing corrective actions are in place
- **Correct blood film specimen**
    - Completed request
    - Labeled with unique ID and matched with the request
- **Safety and waste disposal**
    - Protective clothing, such as gloves and laboratory coat are used.
    - Working space is clear, clean, and ventilated
    - Running water is available and adequate
    - Apparatus are available for disposal of sharps and other contaminated materials.

F.2. Quality Indicators for Malaria RDT

- SOP and job aid in place
- Checked RDTs are used
- Trained personnel is working on malaria RDT
- RDTs are properly stored and transported
- In-time RDTs are used
- EQA participation
- Mechanisms or process for implementing corrective actions are in place
- All used RDTs are discarded in a safe place for incineration

4 REFERENCES

1. World Health Organization. World Malaria report 2016. http://apps.who.int/iris/bitstream/10665/252038/1/9789241511711-eng.pdf?ua=1. Accessed on 11 November, 2017.
2. Zwang J, Olliaro P, Barennes H, Bonnet M, Brasseur P, Bukirwa H, et.al. Efficacy of artesunate-amodiaquine for treating uncomplicated Plasmodium falciparum malaria in sub-Saharan Africa: a multi-center analysis. Malar J 2009; 8:203.
3. World Health Organization. Factsheet on the World Malaria Report 2014. http://www.who.int/malaria/media/world-malaria-report-2016/en/. Uploaded on December 2016. Accessed on November,15 2017.
4. FMOH (2006). National Five-Year Strategic Plan for Malaria Prevention and Control in Ethiopia (2006-2010).
5. FMOH (2014). National Malaria Strategic Plan 2014-2020. pp 80.
6. FMOH/ANVR/WHO (2007). Entomological profile of malaria in Ethiopia.
7. FMOH (2008) - Ethiopian National Malaria Indicator Survey 2007-Technical Summary.
8. FMOH/EPHI/TLCP (2008). Guidelines for Quality Assurance of Smear Microscopy for Tuberculosis Diagnosis (DRAFT).
9. IMaD Ghana MOH (2008). Draft of National Guideline for Laboratory Diagnosis of Malaria.
10. SNNPRS Regional Health Bureau/Malaria Consortium (2008). Implementation Guideline for Malaria Microscopic Diagnosis Quality Assurance. Awassa, September 2008.
11. FMOH (2004). Malaria Diagnosis and Treatment Guidelines for Health Workers in Ethiopia. 2nd Edition. Addis Ababa, July 2004.
12. WHO/SEARO/WPRO. Malaria Light Microscopy. Creating a Culture of Quality a Manual for Quality Assurance of Malaria Microscopy Problem (DRAFT).
13. FMOH/EPHI (2009). Master Plan for the Public Health Laboratory System in Ethiopia (2009-2013). Second Edition. Addis Ababa, January 2009.
14. WHO/USAID (2000). New Perspectives Malaria Diagnosis: report of a joint WHO/USAID informal consultation. Geneva, October 1999.
15. WHO (2009). Malaria Microscopy Quality Assurance Manual. Version 1, February 2009.
16. FMOH 2009 EFY(2016/2017). Annual Performance Report. Version 1.

ICAP
GLOBAL. HEALTH. ACTION.
Columbia University
Mailman School of Public Health