



National Guidelines on
External Quality Assessment - LQAS for
Sputum AFB Microscopy

National Tuberculosis Reference Laboratory
Department of Public Health, Myanmar

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Preface

Tuberculosis is a chronic infectious disease which is still a major global health problem especially in the less developed regions of the world including Myanmar. For the National Tuberculosis Program, the diagnosis as well as monitoring of treatment progress of tuberculosis depends mainly on sputum AFB microscopy.

To have a correct result, the skill of technicians for smear preparation, staining and smear reading play an important role. To improve the quality of work and then to maintain it, microscopy performance needs regular monitoring.

NTP developed the first guidelines on “External Quality Assessment-LQAS for sputum AFB Microscopy” in 2007. In the first book only the Ziehl Neelsen method was mentioned. In 2012 NTP introduced Fluorescence microscopy as an additional tool. Fluorescence microscopy gains more sensitivity and quick reading than bright field microscopy, thus less time is needed for examination.

To assess smear preparation quality, bright field microscopy with Ziehl-Neelsen staining method has six (6) check points termed specimen, staining, cleanliness, size, thickness, and evenness but Fluorescence microscopy can be assessed by five (5) check points except quality of staining. The reporting scale for reading Fluorescence microscopy also differs from that with Ziehl-Neelsen microscopy.

This guideline is a useful tool to have correct results for both Bright field microscopy and Fluorescence microscopy and will be beneficial in our fight against tuberculosis.

Dr.Swe Sett

Deputy Director General (Laboratory)

Abbreviations

| | |
|--------|--|
| AFB | Acid Fast Bacilli |
| APHL | Association of Public Health Laboratories |
| CDC | Centers for Disease Control |
| EQA | External Quality Assessment |
| FM | Fluorescence Microscopy |
| FN | False Negative |
| FP | False Positive |
| HC | Health Center |
| IUATLD | International Union Against Tuberculosis and Lung Disease |
| JICA | Japan International Cooperation Agency |
| KNCV | Koninklijke Nederlandse Cetrale Vereniging ter Bestrijding van tuberculose [KNCV Tuberculosis Foundation] |
| LQAS | Lot Quality Assurance System |
| Lab MO | Laboratory Medical Officer |
| MO | Medical Officer |
| Msp | Microscopist |
| NTP | National Tuberculosis Programme |
| NTRL | National Tuberculosis Reference Laboratory |
| QA | Quality Assurance |
| QC | Quality Control |
| QE | Quantification Error |
| RIT | Research Institute of Tuberculosis |
| SPR | Slide Positivity Rate |
| STLS | Senior Tuberculosis Laboratory Supervisor |
| TMO | Township Medical Officer |
| VF | Visual Field |
| WHO | World Health Organization |
| WPRO | Western Pacific Regional Office |
| ZN | Ziehl- Neelsen |

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INTRODUCTION

In many high TB burden settings, sputum-smear microscopy remains the primary diagnostic technique for evaluating individuals presenting with the signs and symptoms of TB. WHO recommends that TB programmes should use mWRD as the initial diagnostic test for detecting MTBC rather than routine smear microscopy.

The establishment of a broad network of well-functioning peripheral laboratories within the context of the health system and readily accessible to the population is a high priority for any tuberculosis programme. The National Tuberculosis Programme (NTP) has made considerable advances in its effort to control TB in Myanmar. Since 1997 NTP utilizes the DOTS strategy. The NTP activities are implemented through an integration approach with primary health care services. Nationwide DOTS coverage was achieved by the end of Year 2003.

Microscopy errors are likely to result in failure to detect persons with infectious tuberculosis who will then continue to spread infection in the community or giving unnecessary treatment for “non-cases”. Errors in reading of follow-up smears may result in patients being placed on prolonged treatment, or in treatment being discontinued prematurely. Therefore quality assurance of laboratory services including AFB smear microscopy is essential.

Quality Assurance (QA) is a system designed to continuously improve the reliability and efficiency of laboratory services. As defined by both the WHO and the International Union Against Tuberculosis and Lung Disease, a quality assurance programme for AFB smear microscopy has several components. QA is a total system consisting of internal quality control (QC) (where internal monitoring of working practices, technical procedures, equipment, and materials including quality of stains), assessment of performance using external quality assurance (EQA) methods, and continuous quality improvement (QI) of laboratory services.

Since 1997 NTP, Myanmar started to develop the framework for the implementation of quality assessment activities using conventional method in which all positive slides and 10% of the negative slides examined are checked. It was expanded to all regions and states in 1999. The big number of slides examined for quality checking made burden on STLs so that new EQA method based on Lot Quality Assurance System (LQAS)* was introduced in 2007. Sample size was fixed as six slides per month for cross checking according to national TB figures. In 2010 it was conducted in the whole country with different sample sizes for each microscopy center covering both public and private laboratories.

The focus of EQA is on the identification of laboratories where there may be serious problems resulting in poor performance, not on the identification of individual slide errors or the validation of individual patient diagnosis. It is also an important tool for communication with and motivation of laboratory technicians who may otherwise feel isolated in their work. Three methods that can and should be combined to evaluate laboratory performances are:

- On-site Evaluation
- Panel Testing
- Blinded Rechecking

On-site Evaluation

Visits to the peripheral laboratories by trained laboratory personnel from the reference State/Regional laboratory are essential to obtain a realistic assessment of the conditions and skills practiced in the laboratory.

On-site visits by experienced people from a higher-level laboratory provide an opportunity for immediate problem solving, corrective action and on-site retraining.

When poor performance has been identified through on-site evaluation, blinded rechecking or panel testing and additional visits from a higher level laboratory are mandatory.

Frequency of On-site evaluation

| Supervision | | Frequency |
|---------------|---------------|--|
| From | To | |
| Central | State /Region | Annually, whenever rechecking detects major error |
| State /Region | District | At least, 6 monthly Whenever rechecking detects major error |
| District | Township, RHC | At least quarterly, whenever rechecking detects major error |

Panel Testing

Panel testing is a method of EQA that is used to determine whether a laboratory technician can adequately perform AFB smear microscopy. This method evaluates individual performance in staining and reading but not all the laboratory activities. Utilization of panel testing for EQA is less effective than random blinded rechecking of routine slides because it does not monitor routine performance.

In Myanmar for AFB Microscopy panel testing is used under NHL / NTP for State and Regional Hospitals and TB Centers because these institutions do not have routine slides for blinded rechecking. Panel testing is performed to Senior TB Laboratory Supervisors (STLS) who are Laboratory Officers, Medical Technologists and Senior technicians from State and Regional Level designated by The Ministry of Health. Panel testing is not performed as a routine to other level laboratories, as they will have regular on-site evaluation and blinded rechecking by STLS.

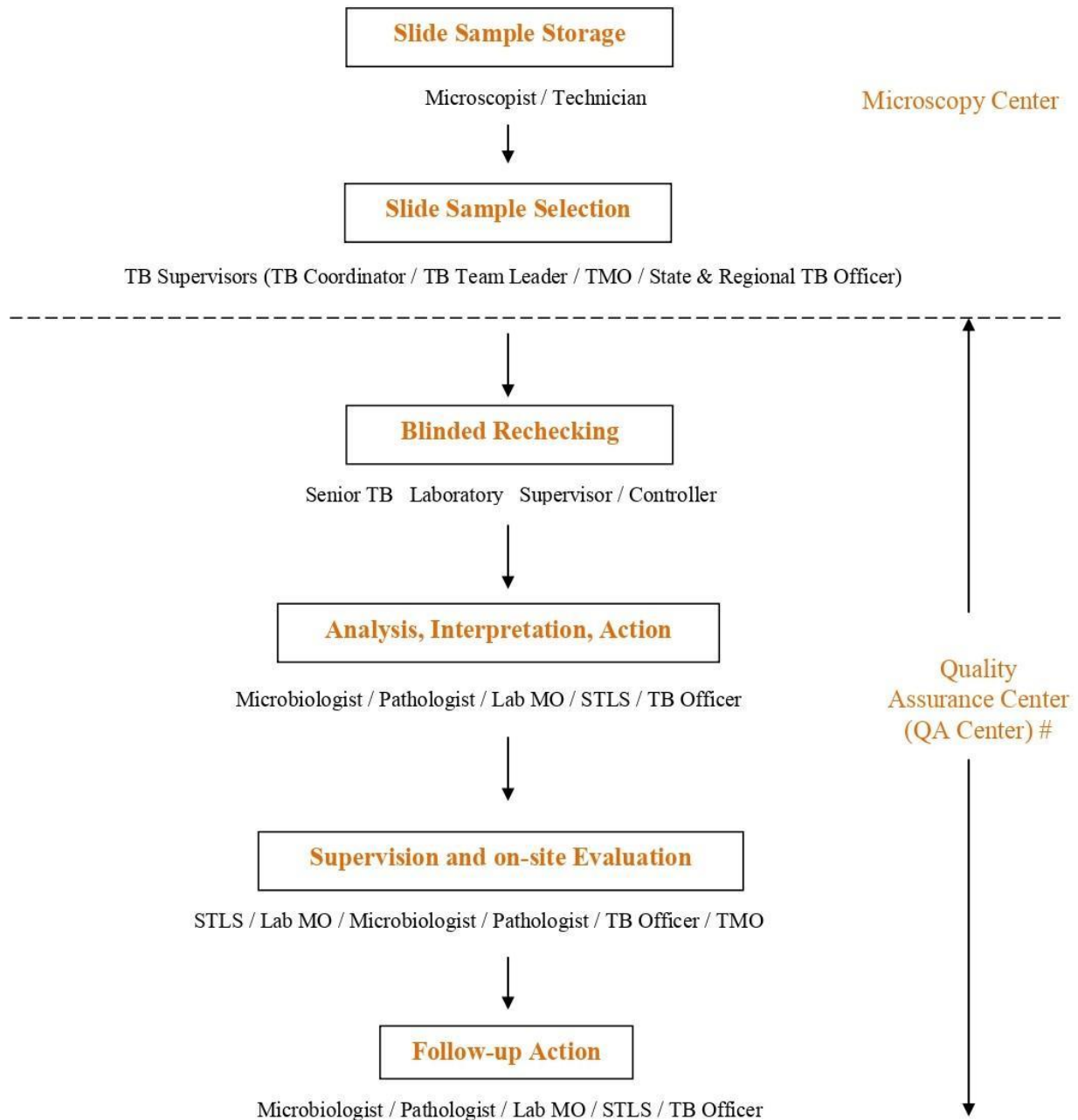
Blinded Rechecking

Blinded rechecking is a process of rereading a sample of slides from a laboratory to assess whether that laboratory has an acceptable level of performance.

Pilot studies had been carried out at Yangon and Mandalay Regions on EQA-(LQAS) System and found that this system can be applied in Myanmar provided there is a national guideline and necessary training given to TB Supervisors. At least once in a quarter visit to the district and peripheral laboratories by TB Supervisors from State and Regional level is required. Laboratory Officials from Central (NTRL) must visit to State and Regional Level at least once in a year.

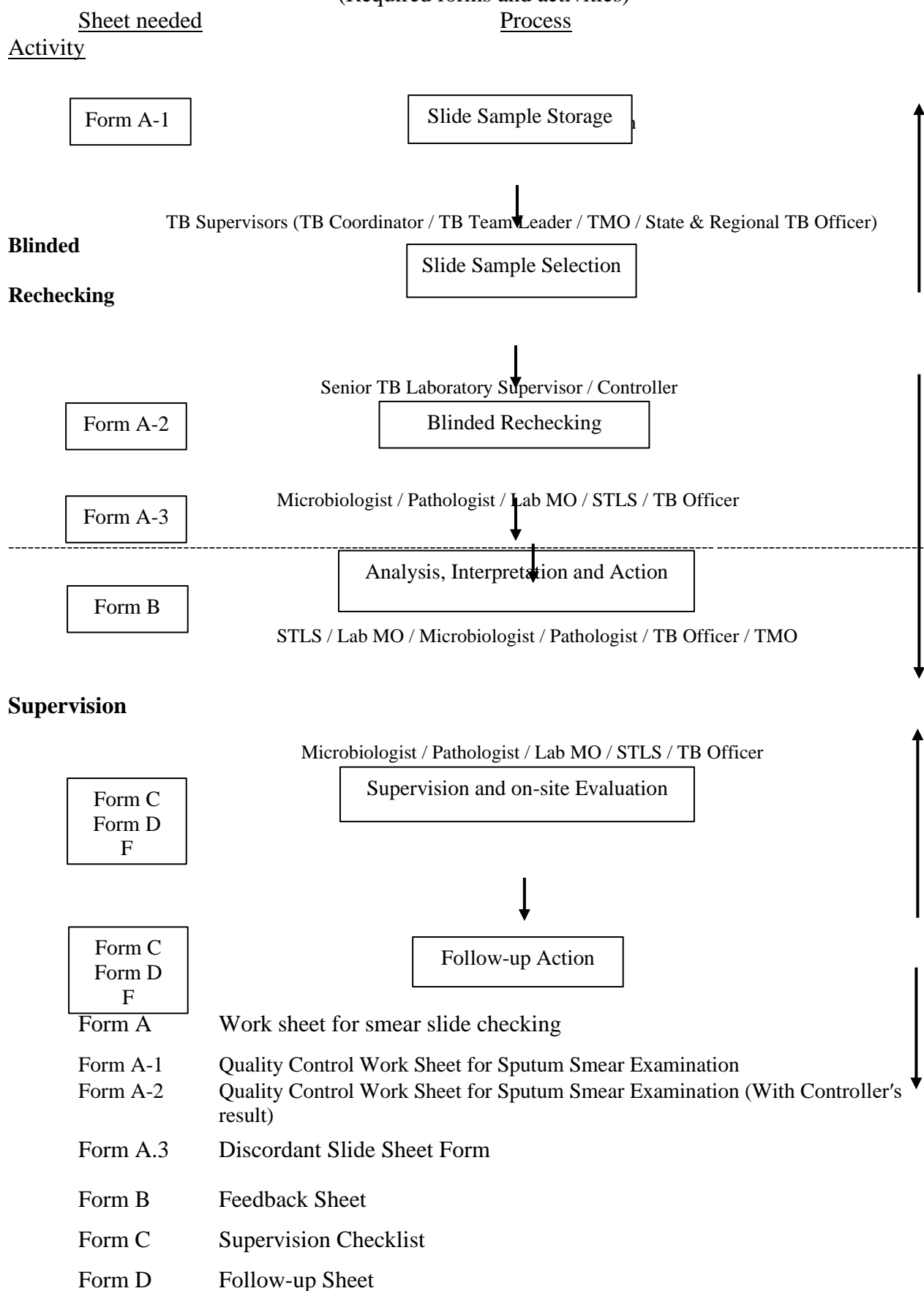
Flowchart of EQA System

(Responsible Person)



QA Center is located at State and Regional level Laboratories and is responsible for effective implementation of quality assurance on AFB microscopy services of peripheral laboratories within its State and Region

Flowchart of EQA System (Required forms and activities)



Operating Procedures

(1) Slide Sample Storage

Responsible person: Microscopist / Laboratory technician

- Remove the oil from the slide with Xylene (needed for slides used by ZN staining method).
- Store all the examined slides chronologically in the slide box as in TB laboratory register until slides are selected and keep away from direct sunlight.

(2) Slide Sample Selection

Responsible person: TB Supervisors – State & Regional TB Officer/

TB Coordinator / TB Team Leader / TMO / who are called slide selector.

- Microscopist / Technician together with the slide boxes, TB Laboratory Register and Form A has to go to the slide selector.
- Select slide samples as determined for a month for each center.
- If the slides examined for one month is less than six (6), all slides must be taken.
- Select the slides from TB Laboratory Register as instructed in Page 9. Ensure that the result is not written on the slide.
- If a particular slide is broken or missing, take the next slide.
- Enter the details of slides in Form A (see Example. 1). This will be known as **Form A data sheet.**
- Take out the selected slides in sequence and transfer to the smaller slide box in the presence of the supervisor (the slide selector).
- Write the name of the microscopy center and month on the slide box.
- Pack the slide box and send it with Form A data sheet to the QA center.
- Leave a duplicate of Form A at the microscopy center.
- Discard all the remaining slides in the slide boxes.

(3) Blinded -Rechecking

Responsible person: STLS /Controller

- Handover the slides and Form A, to the Responsible person of the QA center.
- Record the name of microscopy center, month and slide numbers (but not results) in a new Form A.
- Give the slides together with this new Form A to the Controller, who must not be the person responsible for data entry.

- For QC slides used by the Ziehl-Neelsen (ZN) staining method. The controller must check the quality of smear preparation based on six (6) assessment points both macroscopically and microscopically.
- Read with a bright field microscope to check capability of reading and enter the results in Form A (see Example. 2). This will be known as Form A result sheet.
- All discordant ZN QC slides must be re-stained with the ZN staining method and read again with a bright field microscope.
- For QC slides used by Fluorescence staining method. The controller must check the quality of smear preparation based on five (5) assessment points both macroscopically and microscopically.
- Re-stain all FM QC slides with Fluorescence staining method to check capability of reading.
- Read with a fluorescence microscope and enter the results in Form A result sheet.
- Give the Form A result sheet together with examined slides to the Responsible person of QA center.
- The controller must complete re-reading within one week after receiving the slides.

(Note: For the ZN staining method. All QC slides must be retained after smear assessment in special occasions like MCs where a less experienced person performs FM microscopy or poor quality stains are used.)

(4) Analysis, Interpretation and Action to be taken

Responsible person: Microbiologist / Pathologist / Lab MO / MO / STLS

- The responsible person transcribes the peripheral laboratory results from the data sheet to result sheet.(See Form A Example. 3)
- In case of discrepancy, ask / request the same or another controller to examine the discordant slide and verify the results by using Form A.3 known as discordant slide sheet (see Form A Example. 4)
- Keep all discordant slides for discussion during the next supervisory visit.
- Discard the remaining slides.
- Record the assessment results in Feedback Sheet (Form B).
- Make analysis and interpretation on smear reading and smear preparation by a responsible person.
- Calculate the overall proportion of good / poor smear preparation.
- Include likely explanations as well as suggestions for corrective actions in the feedback. Praise good work. Provide feedback for the discordant slides.

- Review any detected error as a potential indicator of diminished competency and investigate further.

Note : (1) Major errors are seen, it means the need for prompt on-site supervision and also re-training of technicians.

(2) An occasional minor error (quantification) is not a problem, but if this occurs repeatedly or if smear preparation quality is continuously below the acceptable standard of 90%, the laboratory performance should be reassessed.

(5) On- Site Evaluation/ Feedback/ Follow-up

- QA center makes supervisory visit to the microscopy center at least quarterly based on Feedback sheet (Form B). Emphasis is placed on the identification and correction of error found in rechecking. Major error indicates a serious defect in microscopy service of that center. Therefore, once the major error is identified, action must be taken immediately by the QA center, that is within 7 to 10 days after rechecking.
- Send the filled Form B Sheet within 2 - 4 weeks by postal service either to TMO or TB Team Leader who is responsible person of the respective microscopy center. This sheet must be shown to the technician so that he/she will know the mistakes and corrections to be made.
- During supervisory visit take along the discordant slides and fill Form B of that microscopy center for discussion. Record findings, recommendations and actions taken in the Follow-up Sheet (Form D) as reference for the next field visit.
- Leave a duplicate of Form D at the microscopy center.
- The Supervision Checklist for TB Laboratory (Form C) needs to be filled at quarterly visit.

(6) Monitoring purposes

- The consolidated data sheets of each microscopy center (Form 1 and Form 2) are useful to assess the condition and progress of that participating laboratory. Data must be filled monthly or quarterly at QA Center. Regular entry of results is needed for midterm and annual report.
- The consolidated data sheets of each QA Center (Form 3 and Form 4) at State and Regional level will help the State/ Regional TB Officer to monitor the situation of laboratory performance as a whole. This will also indicate the laboratory which needs attention and refresher training.

Determination of Sample Size in Myanmar

In Myanmar, LQAS (Lot Quality Assurance System) sampling method is adopted with 80% sensitivity, 100% specificity and acceptance error (d) = zero (0). Based on the Table “Recommended annual sample sizes.” (See in Appendices) NTP, Myanmar makes Simplified Table of Monthly Sample Sizes (See the Table below) in 2009. Calculation of sample sizes will be made based on annual negative slides and slide positivity rates for each and every microscopy center. The sample sizes will be revised every 3 years.

Since 2010 the NTP, Myanmar started different sample sizes for each and every microscopy center and therefore will be reviewed once every three (3) years. If there is any change, it will be informed.

Simplified Table of Monthly Sample Sizes

| Number of Negative Slides/year | Slide positivity Rate | | |
|--------------------------------------|---------------------------------|-------------------|---------------------|
| | < 7.50% - 7.50% | 7.51% - 12.50% | 12.51% - >12.51% |
| | Number of slides for rechecking | | |
| >500 | 13 | 7 | 6 |
| 501-1000 | 15 | 8 | 6 |
| >1000 | 18 | 9 | 6 |

(80% sensitivity, 100% specificity, ‘0’ acceptance number)

Procedure for Slide Selection

Example:

Today is 15th Sep, 2023

- You are going to select the slides examined for the month of Aug 2023.
- Number of slides to be selected for the month is 6 (six).

The technician must bring the slide boxes and TB Laboratory Register to the person who will select the slides.

- 1) Check the TB Laboratory Register, and determine the number of smear examined in Aug, 2023
- 2) Total number of smears examined is (e.g. 210). Count the number of slides in the slide boxes to make sure there are 210 slides.

3) Sampling interval is
$$\frac{\text{Total number of slides examined}}{\text{Number of slides to be selected}} = \frac{210}{6} = 35$$

- 4) Choose any number below the sampling interval (between 1 to 35).
- 5) Say 3. Therefore, the first slide to be taken is 3rd. slide from the slide box. Then make a circle on the TB Laboratory Register every 35th. Slide counting from 3rd slide.
i.e. 3, 38, 73, 108, 143 and 178.
- 6) Ask the technician to do the following:-
 - a) take out the above slides and put it in a new slide box.
 - b) to fill Form A (The Slide Selector must sign on the form to prove that the slide selection is made by him / her. Signature of lab technician must also be included.
 - c) to discard the remaining slides in the slide boxes.
- 7) Keep the carbon copy of Form A at the Microscopy Center.
Send the slides together with filled Form A to the QA Center.

AFB Slide Reading

WHO and IUATLD recommended quantification scale

| Reporting scale for Bright Field Microscopy (Ziehl - Neelsen Method) | |
|--|--|
| 1,000 X magnification (One length = 2 cm = 100 fields) | |
| Reporting scale | AFB seen |
| (3+) | More than 10 AFB per field in at least 20 fields |
| (2+) | 1- 10 AFB per field in at least 50 fields |
| (1+) | 10-99 AFB per field in at least 100 fields |
| (Scanty) Report actual number | 1-9 AFB per 100 fields |
| Negative = neg | No AFB seen in at least 100 fields |

| Reporting Scale For Fluorescence Microscopy (Auramine Method) | |
|---|--|
| 200 X magnification (One length = 2 cm = 30 fields) | |
| Reporting scale | AFB seen |
| (3+) | More than 250 AFB per field on average |
| (2+) | 25-250 AFB per field on average |
| (1+) | 3-24 AFB per field on average |
| (Scanty) Report actual number | 5-49 AFB per one length if found (1- 4 AFB) in one line (Confirmation needed**) |
| Negative = neg | No AFB seen in one length |

****Confirmation required by another technician or prepare another smear, stain and read**

Note(1); for FM microscopy , to check reading, use the 20 x objective to scan the smear and the 40 x objective for confirming suspicious objects.

Note(2); The typical appearance of an AFB is a long, slender, slightly curved rod but variable in shape and staining intensity.

Interpretation of Readings

Quality of reading will be assessed with the type of error (major errors/ minor errors) found. major and minor errors must be looked for. These are HF (+), HF(-), LF(+), LF(-) and QE. No error in any type is considered as optimal performance. Any major error indicates unacceptable performance and triggers an evaluation and corrective action. It is possible that no significant problems in laboratory practice will be found, and performance trends should be monitored over time. Repeated occurrence of similar minor errors is required for further evaluation.

False positive (+) result = by Laboratory technician at microscopy center but read negative by Controller

False negative (-) result = by Laboratory technician at microscopy center but read positive by Controller

Classification of errors

Bright field Microscopy

| Result by controller | Result by Microscopist | | | | | Total |
|----------------------|------------------------|----------------------|---------|---------|---------|-------|
| | 0 | 1-9 AFB / 100 fields | 1+ | 2+ | 3+ | |
| 0 | Correct | LF (+) | HF (+) | HF (+) | HF (+) | |
| 1-9 AFB/ 100 f | LF (-) | Correct | Correct | QE | QE | |
| 1+ | HF (-) | Correct | Correct | Correct | QE | |
| 2+ | HF (-) | QE | Correct | Correct | Correct | |
| 3+ | HF (-) | QE | QE | Correct | Correct | |
| Total | | | | | | |

Fluorescence Microscopy

| Result by controller | Result by Microscopist | | | | | Total |
|-----------------------|------------------------|-----------------------|---------|---------|---------|-------|
| | 0 | 5-49 AFB / one length | 1+ | 2+ | 3+ | |
| 0 | Correct | LF (+) | HF (+) | HF (+) | HF (+) | |
| 5-49 AFB / one length | LF (-) | Correct | Correct | QE | QE | |
| 1+ | HF (-) | Correct | Correct | Correct | QE | |
| 2+ | HF (-) | QE | Correct | Correct | Correct | |
| 3+ | HF (-) | QE | QE | Correct | Correct | |
| Total | | | | | | |

| | | | |
|---------|---|----------------------|---|
| Correct | = | Consistent result | (same result by both Microscopist and Controller) |
| LF (+) | = | Low False Positive | (Minor Error) |
| LF (-) | = | Low False Negative | (Minor Error) |
| QE | = | Quantification Error | (Minor Error) |
| HF (+) | = | High False Positive | (Major Error) |

Possible Causes and Suggested Actions

| Type of Error | Possible Causes | Suggested Actions |
|---|--|---|
| HFN (major errors) | - Insufficient time spent for scanning smear | - Check scanning manner |
| | - Poor smearing technique (very thick smear) | - Evaluate quality of smear preparation |
| | - Staining problems, poor stain, insufficient staining time or heating (pale AFB, insufficient contrast in background) | - Check staining performance and stains. Use new staining reagents |
| | - Defective microscope | - Check microscope (position of Condenser, Diaphragm for poor light). Test with positive smear. |
| | - Mistranscription of the result | - Check laboratories register and compare with QC list. |
| HFP (major errors) | - Artifact (e.g., stain deposits or crystals) incorrectly interpreted as AFB | - Filter carbol fuchsin/Auramine O and/ or prepare new stains |
| | - AFB carried over in immersion oil from a previous positive smear for ZN method | - Clean x 100 objective lens and check microscopy performance |
| | - Staining problem and fading of Fuchsin stain of AFB | - Restain slides to check for fading |
| | - Mistranscription of the result | - Check laboratory register and compare with QC list. |
| LFN LFP QE (minor errors) | - Insufficient time spent in scanning smear | - Check scanning manner |
| | - Technician does not understand scoring system | - Check AFB reporting scale |
| | - Poor staining technique | - Check reagents and staining technique |
| | - Defective microscope | - Check microscope |

HFN = High False Negative

HFP = High False Positive

QE = Quantification Error

LFN = Low False Negative

LFP = Low False Positive

Possible Causes of False Reading Results

| Check point | Causes | False Negative (FN) | False Positive (FP) |
|-------------------|---|--|--|
| Smear Size | - Too big - Too small | <input type="checkbox"/> <input type="checkbox"/> | |
| Smear Evenness | - Uneven - Sloughed-off | <input type="checkbox"/> <input type="checkbox"/> | |
| Smear Thickness | - Too thick - Too thin | <input type="checkbox"/> <input type="checkbox"/> | |
| Smear Cleanliness | - Dirt - Artifact | <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |
| Sputum Quality | - Saliva | <input type="checkbox"/> | |
| Staining | - Overheating - Insufficient heating/ time - Poor decolourization | <input type="checkbox"/> <input type="checkbox"/> | <input type="checkbox"/> <input type="checkbox"/> |

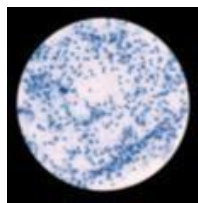
Main Factors leading to false results

| Step | False (-) | False (+) |
|------------------------------|--|---|
| Specimen | - Poor quality & quantity | - Error in handling - Artifact in specimen |
| Smear Preparation & Staining | - Thick, uneven and too little material with too thin smear preparation - Insufficient heating /staining - Intensive counterstaining | - Overheated staining - Inadequate decolourization - Deposit/ Cristal in stains |
| Reading | - Insufficient scanning - Defective microscope - Erratic attitude - Physical problem | - Transfer of positive smear particle - Erratic attitude |
| Recording | - Mistranscription - Mislabeling of specimen | - Mistranscription - Mislabeling of specimen |

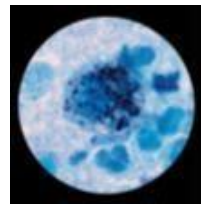
Assessment Points of Smear Slide Preparation

Quality of smear slide preparation will be evaluated in terms of six (6) check points mentioned below. All these six (6) check points will be used for ZN QC smears. Proportion of good smear preparation for each assessment point should be 90% or more. Stained smear slides can be evaluated whether they are good or poor in terms of the dominance of the following checkpoints in the smear area macroscopically and microscopically.

- 1) Specimen Quality: The presence of dust cell (macrophage) or presence of more than 25 leukocytes per field at total magnification of x 100 are observed.**

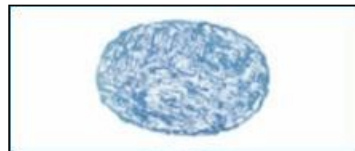


Leucocyte (x 100)



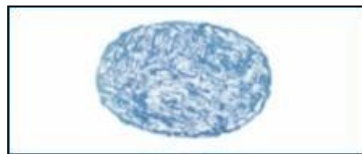
Dust cell (x 1,000)

- 2) Smear Size: Approximately 2 x 3 cm in size.**

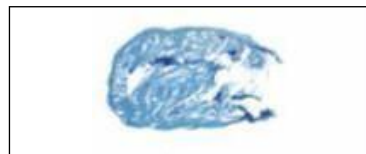


size of 2cm x 3cm

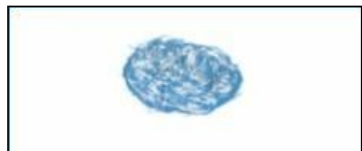
- 3) Evenness: Smear area is not extremely uneven or the smear is not sloughed off.**



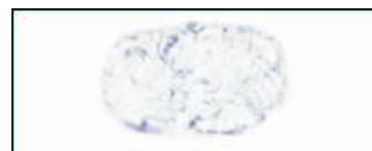
Good



Sloughed off

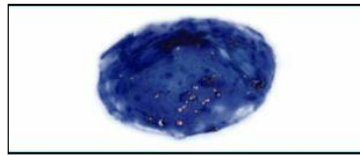
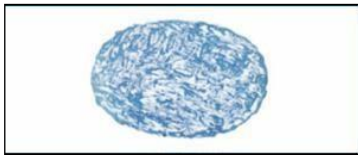
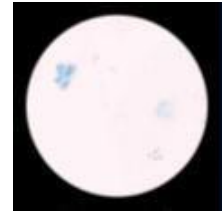
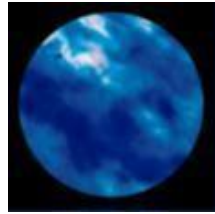
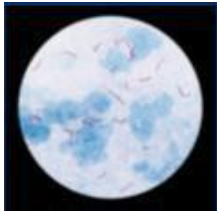


Good



Uneven

4) Smear Thickness: The whole depth of the smear layer can be focused sharply in each field.

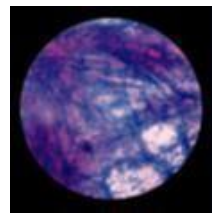
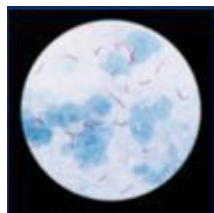


Good

Too thick

Too thin

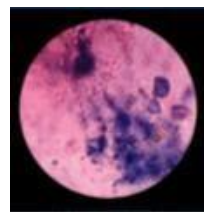
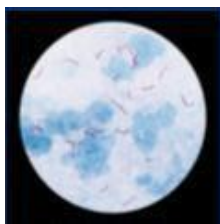
5). Staining Quality: AFB background is clearly distinguished (over/under staining).



Good

Under decolourization

(6). Smear Cleanliness: Presence of stain deposit, dirt, debris, etc. should be avoided as much as possible so as not to cause interference in reading.

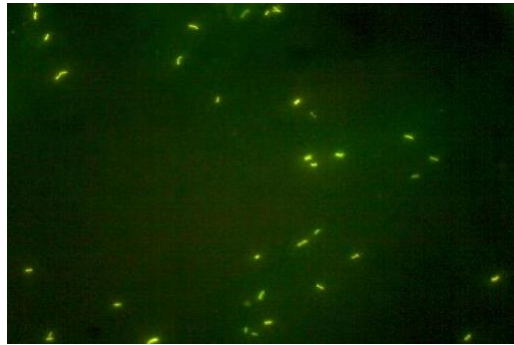


Good

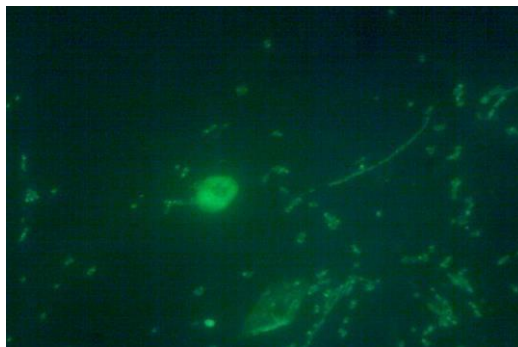
Dirt with crystal

Note: Smear preparation quality of FM QC smears will be assessed with five (5) check points except staining quality and it must be used with 10x objective of fluorescence microscope by ordinary light, not by fluorescent light. Ways of assessment are the same as the ZN method.

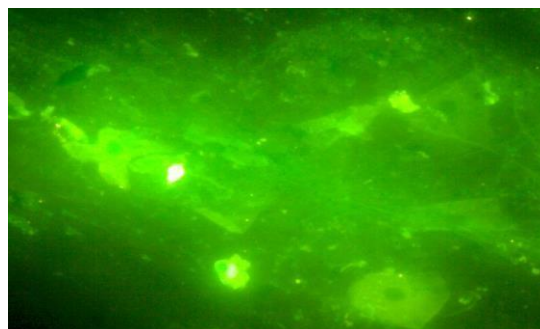
- a. Auramine stained good smear with 20 x magnification



- b. Auramine stained smear with stain deposit



- c. Auramine stained smear with under decolorization



Feedback

The primary purpose of a rechecking program is to improve the overall quality of smear microscopy, therefore regular and timely feedback to the peripheral laboratory is essential if any improvements in performance are expected. Annual reports should be sent to the regional health authority, district physician as well as the laboratory technicians. Although final analysis of the results and conclusions have to await completion of rechecking of the whole (annual) sample, preliminary observations, feed-back and remedial action will often be possible at the end of each sampling period. This will be obvious in laboratories with very poor performance where immediate problem solving is most urgently needed. If results from the controllers are to be perceived as credible, and offer an opportunity to improve performance, feedback should include returning slides with discordant results to be reread by the original technicians. This gives them a chance to show what they interpreted as AFB, or to be shown AFB they have missed. Poor performance should always be investigated to identify the reason. The investigation should include on-site evaluation visits to determine the source of the problem. In most programs, the district supervisor will bring the rechecking results to the peripheral laboratory during the routine visit, which provides an opportunity to discuss results, recognize good performance and find potential solutions to any problems. Visits by the supervising laboratory offer the best opportunity to review results of rechecking with the technicians in the peripheral laboratories, identify potential sources of error, and implement corrective action. For this reason, on-site supervisory visits by experienced staff from the intermediate or national laboratory are recommended at least once a year, and more frequently if significant problems are identified. All potential sources of error should be considered, including quality of stains and staining procedure, quality of microscopes, and administrative procedures that may contribute to recording errors. All problems contributing to errors must be resolved. Possible causes of errors and suggested evaluation steps are listed in Appendix E. Remedial training must be provided for technicians unable to properly identify AFB in smears. In some cases, no obvious problem will be detected. Supplemental panel testing and ongoing blinded rechecking are recommended to monitor performance. Due to the many variables that can affect laboratory performance, and the potential for these factors to change over time, it is recommended that rechecking be continued even after consistently good performance is achieved.

Appendices

1) Forms

| | |
|--------|---|
| Form A | Worksheet for smear slide checking |
| Form B | Feedback Sheet |
| Form C | Supervision Checklist for TB Laboratory |
| Form D | Follow-up Sheet |

2) Consolidated Data Sheets

| | | |
|---------|-------------------------|-----------------------------|
| Form 1: | Smear Slide Preparation | by Microscopy Center |
| Form 2: | Smear Slide Reading | by Microscopy Center |
| Form 3: | Smear Slide Reading | (State/ Division QA Center) |
| Form 4: | Smear Slide Preparation | (State/ Division QA Center) |

3) Example (Filling of Forms)

National Tuberculosis Programme, Myanmar

Quality Control Work Sheet for Sputum Smear Examination

Microscopy Center: _____

District: _____

Month: _____

Year: _____

| Sr. No. | Slide No. | AFB result by | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
|------------|-----------|------------------|-----|---------------------|----|----------|----|-------------|----|------------|----|-----------|----|----------|----|
| | | Msp | Con | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1 | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | |
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| 18 | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |

Msp = Microscopist

Con = Controller

Gd = Good

Pr = Poor

B = Too big

S = Too small

Tk = Too thick

Tn = Too thin

O = Over decolorization

U = Under decolorization

Date: _____

Analyzed by (with signature): _____

National Tuberculosis Programme, Myanmar

Quality Control Work Sheet for Sputum Smear Examination

(With controller's result)

Microscopy Center: _____

District: _____

Month: _____

Year: _____

| Sr. No. | Slide No. | AFB result by | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
|------------|-----------|------------------|-----|---------------------|----|----------|----|-------------|----|------------|----|-----------|----|----------|----|
| | | Msp | Con | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1 | | | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | | | |
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| 13 | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |

Msp = Microscopist

Con = Controller

Gd = Good

Pr = Poor

B = Too big

S = Too small

Tk = Too thick

Tn = Too thin

O = Over decolourization

U = Under decolourization

Remarks: by controller

Date: _____

Analyzed by (with signature): _____

National Tuberculosis Programme, Myanmar

External Quality Assessment Worksheet for Sputum Smear Examination Discordant Slides Form

Microscopy Center:

District:

Year:

| Sr. No. | Month | Discordant Slide No. | AFB result by | | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | | Thickness | | | Evenness |
|---------|-------|----------------------|---------------|-----------|-----|------------------|----|----------|----|-------------|----|------------|----|----|-----------|----|----|----------|
| | | | Msp | STLS /Con | Ump | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | |
| 1. | | | | | | | | | | | | | | | | | | |
| 2. | | | | | | | | | | | | | | | | | | |
| 3. | | | | | | | | | | | | | | | | | | |
| 4. | | | | | | | | | | | | | | | | | | |
| 5. | | | | | | | | | | | | | | | | | | |
| 6. | | | | | | | | | | | | | | | | | | |
| 7. | | | | | | | | | | | | | | | | | | |
| 8. | | | | | | | | | | | | | | | | | | |
| 9. | | | | | | | | | | | | | | | | | | |
| 10. | | | | | | | | | | | | | | | | | | |
| 11. | | | | | | | | | | | | | | | | | | |
| 12. | | | | | | | | | | | | | | | | | | |
| 13. | | | | | | | | | | | | | | | | | | |
| 14. | | | | | | | | | | | | | | | | | | |
| 15. | | | | | | | | | | | | | | | | | | |

(note) Msp = Microscopist STLS = Senior TB laboratory Supervisor Con=Controller Ump

= Umpire reader Gd = Good

Pr = Poor

B = Too big

S = Too

small

Tk = Too thick Tn = Too thin

O = Over decolourization U = Under decolourization

Comments / Suggestions by umpire reader

Date: -----

Analyzed by (with signature): -----

| National Tuberculosis Programme, Myanmar | | | | | | Form B 1 |
|--|------------------------|--------------------------|------------------------|---------------------------|----------|-------------|
| External Quality Assessment | | | | | | |
| Feedback Sheet (Bright Field Microscopy) | | | | | | |
| Microscopy Center: | | | Month/ Quarter/ Year: | | | |
| Smear Reading | | | | | | |
| Result by Controller | Result by Microscopist | | | | | Total |
| | Neg | 1-9 AFB/ 100f | 1+ | 2+ | 3+ | |
| Neg | | LF (+) | HF (+) | HF (+) | HF (+) | |
| 1-9 AFB/ 100f | LF (-) | | | QE | QE | |
| 1+ | HF (-) | | | | QE | |
| 2+ | HF (-) | QE | | | | |
| 3+ | HF (-) | QE | QE | | | |
| Total | | | | | | |
| Classification of errors | | Number | No. of slide discussed | | | |
| Major Error | HF (+) | | | | | |
| | HF (-) | | | | | |
| Minor Error | LF (+) | | | | | |
| | LF (-) | | | | | |
| | QE | | | | | |
| Total No. of errors | | | | | | |
| Smear Preparation (Total number of slides rechecked =) | | | | | | |
| | Good | | Poor | | | |
| | no. | % | no. | % | | |
| Specimen Quality | | | | | | |
| Staining | | | | | O (%) | U (%) |
| Cleanliness | | | | | | |
| Thickness | | | | | Tk (%) | Tn (%) |
| Size | | | | | S (%) | B (%) |
| Evenness | | | | | | |
| Good = acceptable | | O = Over decolourization | | U = Under decolourization | | |
| Tk = Too thick | | Tn = Too thin | | S = Too small | | B = Too big |
| Comments for Improvement: | | | | | | |
| | | | | | | |
| Date report submitted: | | | Report by: | | | |

External Quality Assessment

Feedback Sheet (Fluorescence Microscopy)

Microscopy Center: _____ Month/ Quarter/ Year: _____

Smear Reading

| Result by Controller | Result by Microscopist | | | | | Total |
|----------------------|------------------------|---------------|----------|----------|----------|-------|
| | Neg | 5-49 AFB/ 20f | 1+ | 2+ | 3+ | |
| Neg | | LF (+) | HF (+) | HF (+) | HF (+) | |
| 5-49 AFB/ 20 f | LF (-) | | | QE | QE | |
| 1+ | HF (-) | | | | QE | |
| 2+ | HF (-) | QE | | | | |
| 3+ | HF (-) | QE | QE | | | |
| Total | | | | | | |

| Classification of errors | | Number | No. of slide discussed |
|--------------------------|----------|--------|------------------------|
| Major Error | HF (+) | | |
| | HF (-) | | |
| Minor Error | LF (+) | | |
| | LF (-) | | |
| | QE | | |
| Total No. of errors | | | |

Smear Preparation (Total number of slides rechecked =)

| | Good | | Poor | | |
|------------------|------|---|------|---|-------------------------|
| | no. | % | no. | % | |
| Specimen Quality | | | | | |
| Staining | | | | | |
| Cleanliness | | | | | |
| Thickness | | | | | Tk (%) Tn (%) |
| Size | | | | | S (%) B (%) |
| Evenness | | | | | |

Good = acceptable

O = Over decolourization

U = Under decolourization

Tk = Too thick

Tn = Too thin

S = Too small

B = Too big

Comments for Improvement:

Date report submitted: _____

Report by: _____

| National Tuberculosis Programme | | Form C |
|--|---|---|
| Supervision Check List for TB Laboratory | | |
| | | Date: |
| Name of Township: | | |
| | | <input type="checkbox"/> General Laboratory |
| | | <input type="checkbox"/> TB Laboratory |
| | | |
| Sr. No. | Questions | Answers |
| 1 | Interview with laboratory staff ●How many staff work in the laboratory? Any vacancy? | |
| | ●Have they received NTP training? When? | |
| | ●Do they have the NTP laboratory manual? | |
| 2 | Sputum Collection ● When do patients cough up the sputum specimens? | |
| | ●How many sputum specimens are collected from each presumptive TB? | |
| 3 | Smear request form ●How are smears requested and reported? | |
| | ●Is the NTP smear request form used? | |
| 4 | Sputum containers ●Are there adequate supplies? | |
| | ●Are they marked properly (laboratory number on the side) ? | |
| 5 | Laboratory register ●Is the NTP laboratory register used? | |
| | ●Is it filled completely? | |
| | ●Do negative presumptive TB have 2 negative smears? | |
| | ●Do positive cases have 1 positive smear? | |
| | ●Are positive results written in red? | |
| | ●How many smear (diagnosis and follow - up) were examined recently? | |
| | ●Do they put township TB register number in remark column of lab. register? | |
| 6 | Slides ● Are there adequate supplies? | |
| | ●Is the laboratory number marked on the slide properly? | |
| | ●Check some positive and negative smears are they smeared, stained and reported correctly? | |
| 7 | Reagents ●Are there sufficient quantities of reagents? | |
| | ●Are bottles label with the name,date of preparation and expiry ? | |

| | | |
|----|---|--------------------|
| | | |
| 8 | Microscope ●Type (Bright Field Microscope binocular/ monocular) ●Light source (electricity/day light) (Fluorescence Microscope) ●Condition (function/not) | |
| | Quality Control ●Are slides kept for quality control? | |
| | ●Are there sufficient slide boxes? | |
| | ●How often are slides sent for quality control? | |
| 9 | ●How are slides sampled for quality control? | |
| | ●How long are the slides kept before sending for quality control? | |
| | ●Has the laboratory received feed-back results of quality control? | |
| 10 | Disposal ●Method of waste disposal (burial/ burning) | |
| | Others: | |
| | Problems: | |
| | Suggestion Given: | |
| | | |
| | | |
| | | |
| | | |
| | | Signature: |
| | | Name/ Designation: |
| | Original to: - Microbiologist, NTP | |
| | Copy to: - State/ Regional TB Officer | |
| | - TMO or TB Team Leader | |

| National Tuberculosis Programme, Myanmar | | | | | | | | | | | | | | Form (1) | | | | |
|--|------|-------------------------|-------|---------------|---------|--------------|-------|-------|---------|-------|-------|-------|---------|----------|-------|-------|---------|--------|
| Smear Slide Preparation by Microscopy Center | | | | | | | | | | | | | | | | | | |
| Microscopy Center: | | | | | | | | | | | | | | Year: | | | | |
| Month | | 1 | 2 | 3 | 1st Qtr | 4 | 5 | 6 | 2nd Qtr | 7 | 8 | 9 | 3rd Qtr | 10 | 11 | 12 | 4th Qtr | Annual |
| Slide no. for EQA | n | | | | | | | | | | | | | | | | | |
| | % | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) |
| Specimen Quality | Good | | | | | | | | | | | | | | | | | |
| | Poor | | | | | | | | | | | | | | | | | |
| Staining | Good | | | | | | | | | | | | | | | | | |
| | O | | | | | | | | | | | | | | | | | |
| | U | | | | | | | | | | | | | | | | | |
| Cleanliness | Good | | | | | | | | | | | | | | | | | |
| | Poor | | | | | | | | | | | | | | | | | |
| Thickness | Good | | | | | | | | | | | | | | | | | |
| | Tk | | | | | | | | | | | | | | | | | |
| | Tn | | | | | | | | | | | | | | | | | |
| Size | Good | | | | | | | | | | | | | | | | | |
| | S | | | | | | | | | | | | | | | | | |
| | B | | | | | | | | | | | | | | | | | |
| Evenness | Good | | | | | | | | | | | | | | | | | |
| | Poor | | | | | | | | | | | | | | | | | |
| | | O: Over decolorization | | Tk: Too thick | | S: Too small | | | | | | | | | | | | |
| | | U: Under decolorization | | Tn: Too thin | | B: Too big | | | | | | | | | | | | |

| National Tuberculosis Programme, Myanmar | | | | | | | | | | | | | | Form (2) | | | |
|--|-------|-------|-------|---|-------|-------|-------|---|-------|-------|-------|---------|-------|----------|-------|---------|--------|
| Smear Slide Reading by Microscopy Center | | | | | | | | | | | | | | | | | |
| Microscopy Center: | | | | | | | | | | | | | | | Year: | | |
| Month | 1 | 2 | 3 | 1st Qtr | 4 | 5 | 6 | 2nd Qtr | 7 | 8 | 9 | 3rd Qtr | 10 | 11 | 12 | 4th Qtr | Annual |
| Slide no. | | | | | | | | | | | | | | | | | |
| for QA | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) |
| (-) by Mx | | | | | | | | | | | | | | | | | |
| (+) by Mx | | | | | | | | | | | | | | | | | |
| Correct | | | | | | | | | | | | | | | | | |
| HF (+) | | | | | | | | | | | | | | | | | |
| HF (-) | | | | | | | | | | | | | | | | | |
| LF (+) | | | | | | | | | | | | | | | | | |
| LF (-) | | | | | | | | | | | | | | | | | |
| QE | | | | | | | | | | | | | | | | | |
| Total * n | | | | | | | | | | | | | | | | | |
| Error % | () | () | () | () | () | () | () | () | () | () | () | () | () | () | () | () | () |
| HF (+) = High False Positive = Major Error | | | | LF (+) = Low False Positive = Minor Error | | | | QE = Quantification Error = Minor Error | | | | | | | | | |
| HF (-) = High False Negative = Major Error | | | | LF (-) = Low False Negative = Minor Error | | | | | | | | | | | | | |
| * Total error = Major error + Minor error | | | | n= number | | | | | | | | | | | | | |

| National Tuberculosis Programme, Myanmar | | | | | | | | | | | | Form (3) | |
|---|--------------|-------------|-------|--|-------|-------------|---|---|--|--|--|-----------------------|--|
| External Quality Assessment | | | | | | | | | | | | | |
| Smear Slide Reading (State/Region, QA Center) | | | | | | | | | | | | | |
| State/ Region: | | | | | | | | | | | | Month/ Quarter/ Year: | |
| Microscopy Center | Slide for QA | Major Error | | Minor Error | | Major Error | | No. of slides discussed | | | | | |
| | | HF(+) | HF(-) | LF(+) | LF(-) | (n) | % | | | | | | |
| 1 | | | | | | | | | | | | | |
| 2 | | | | | | | | | | | | | |
| 3 | | | | | | | | | | | | | |
| 4 | | | | | | | | | | | | | |
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| 18 | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | |
| Total | | | | | | | | | | | | | |
| HF(+) = High False Positive = Major Error | | | | LF(+) = Low False Positive = Minor Error | | | | QE = Quantification Error = Minor Error | | | | | |
| HF(-) = High False Negative = Major Error | | | | LF(-) = Low False Negative = Minor Error | | | | | | | | | |

External Quality Assessment

Smear Slide Preparation(State/Region, QA Center)

| State/ Region: _____ | | Month/ Quarter/ Year: _____ | | | | | | | | | | | | | | | |
|----------------------|--------------|-----------------------------|------|---------------|---|--------------|------|------------|------|------|----|----------|---|---|------|------|--|
| Microscopy Center | Slide for QA | Specimen Qty | | Staining | | Cleanliness | | Thickness | | Size | | Evenness | | | | | |
| | | Good | Poor | Good | O | U | Good | Poor | Good | Tk | Tn | Good | S | B | Good | Poor | |
| 1 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 2 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 3 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 4 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 5 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 6 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 7 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 8 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 9 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| 10 | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| Total | n | | | | | | | | | | | | | | | | |
| | % | | | | | | | | | | | | | | | | |
| | | O : Over decolourization | | Tk: Too thick | | S: Too small | | n = number | | | | | | | | | |
| | | U: Under decolourization | | Tn: Too thin | | B: Too big | | | | | | | | | | | |

| Example 1 | | | | | | | | | | | | Form A.1 | | | |
|---|-----------|------------------|-----|--------------------------|----|---------------------------|----|-------------|----|---------------|----|------------------------------|----|----------|----|
| National Tuberculosis Programme, Myanmar | | | | | | | | | | | | | | | |
| Quality Control Work Sheet for Sputum Smear Examination | | | | | | | | | | | | | | | |
| (With Microscopist's Result) | | | | | | | | | | | | | | | |
| Microscopy Center: <u>Dagon Myo Thit (South)</u> | | | | | | | | | | | | District: <u>East Yangon</u> | | | |
| Month: <u>January</u> | | | | | | | | | | | | Year: <u>2023</u> | | | |
| Sr. No. | Slide No. | AFB result by | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
| | | Msp | Con | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1 | 23-006-1 | neg | | | | | | | | | | | | | |
| 2 | 23-042-2 | neg | | | | | | | | | | | | | |
| 3 | 23-103-1 | neg | | | | | | | | | | | | | |
| 4 | 23-144-2 | neg | | | | | | | | | | | | | |
| 5 | 23-159-1 | neg | | | | | | | | | | | | | |
| 6 | 23-261-2 | neg | | | | | | | | | | | | | |
| 7 | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |
| Msp = Microscopist | | Con = Controller | | Gd = Good | | Pr = Poor | | B = Too big | | S = Too small | | | | | |
| Tk = Too thick | | Tn = Too thin | | O = Over decolourization | | U = Under decolourization | | | | | | | | | |
| Remarks: by controller | | | | | | | | | | | | | | | |
| Date: _____ Analyzed by (with signature): _____ | | | | | | | | | | | | | | | |
| Slide selection made by: <u>Dr. A</u> | | | | | | | | | | | | | | | |

National Tuberculosis Programme, Myanmar

Quality Control for Sputum Smear Examination

(With controller's result)

Microscopy Center: Dagon Myo Thit (South)District: East YangonMonth: January

Year: _____

| Sr. No. | Slide No. | AFB result by | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
|---------|-----------|---------------|-------|------------------|----|----------|----|-------------|----|------------|----|-----------|----|----------|----|
| | | Msp | Con | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1 | 23-006-1 | | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 2 | 23-042-2 | | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 3 | 23-103-1 | | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 4 | 23-144-2 | | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 5 | 23-159-1 | | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 6 | 23-261-2 | | 5 AFB | ✓ | | ✓ | | ✓ | | | S | | Tn | | ✓ |
| 7 | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |

Msp = Microscopist

Con = Controller

Gd = Good

Pr = Poor

B = Too big

S = Too small

Tk = Too thick

Tn = Too thin

O = Over decolourization

U = Under decolourization

Remarks: by controller

Date: _____

Analyzed by(with signature): _____

| Example 3 | | | | | | | | | | | | Form A.2 | | | |
|---|-----------|------------------|-------|--------------------------|----|---------------------------|----|-------------|----|---------------|----|------------------------------|----|----------|----|
| National Tuberculosis Programme, Myanmar | | | | | | | | | | | | | | | |
| Quality Control Work sheet for Sputum Smear Examination | | | | | | | | | | | | | | | |
| (With controller's result) | | | | | | | | | | | | | | | |
| Microscopy Center : <u>Dagon Myo Thit (South)</u> | | | | | | | | | | | | District: <u>East Yangon</u> | | | |
| Month: <u>January</u> | | | | | | | | | | | | Year : _____ | | | |
| Sr. No. | Slide No. | AFB result by | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
| | | Msp | Con | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1 | 23-006-1 | neg | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 2 | 23-042-2 | neg | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 3 | 23-103-1 | neg | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 4 | 23-144-2 | neg | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 5 | 23-159-1 | neg | neg | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | | ✓ | |
| 6 | 23-261-2 | neg | 5 AFB | ✓ | | ✓ | | ✓ | | | S | | Tn | | ✓ |
| 7 | | | | | | | | | | | | | | | |
| 8 | | | | | | | | | | | | | | | |
| 9 | | | | | | | | | | | | | | | |
| 10 | | | | | | | | | | | | | | | |
| 11 | | | | | | | | | | | | | | | |
| 12 | | | | | | | | | | | | | | | |
| 13 | | | | | | | | | | | | | | | |
| 14 | | | | | | | | | | | | | | | |
| 15 | | | | | | | | | | | | | | | |
| 16 | | | | | | | | | | | | | | | |
| 17 | | | | | | | | | | | | | | | |
| 18 | | | | | | | | | | | | | | | |
| 19 | | | | | | | | | | | | | | | |
| 20 | | | | | | | | | | | | | | | |
| Msp = Microscopist | | Con = Controller | | Gd = Good | | Pr = Poor | | B = Too big | | S = Too small | | | | | |
| Tk = Too thick | | Tn = Too thin | | O = Over decolourization | | U = Under decolourization | | | | | | | | | |
| Comments/suggestions by controller | | | | | | | | | | | | | | | |
| Date: _____ Analyzed by(with signature): _____ | | | | | | | | | | | | | | | |

National Tuberculosis
Programme, Myanmar

**External Quality Assessment Work Sheet for Sputum Smear Examination
Discordant Slides Form**

Microscopy Center: Dagon Myo Thit (South)

District; East District
Year:

| Sr. No. | Month | Discordant Slide No. | AFB result by | | | Specimen Quality | | Staining | | Cleanliness | | Smear Size | | Thickness | | Evenness | |
|------------|-------|-------------------------|---------------|--------------|-----|---------------------|----|----------|----|-------------|----|---------------|----|-----------|----|----------|----|
| | | | Msp | STLS /Con | Ump | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr | Gd | Pr |
| 1. | Jan | 23 - 261-2 | 5AFB | neg | neg | √ | | √ | | √ | | | S | | Tn | | √ |
| 2. | | | | | | | | | | | | | | | | | |
| 3. | | | | | | | | | | | | | | | | | |
| 4. | | | | | | | | | | | | | | | | | |
| 5. | | | | | | | | | | | | | | | | | |
| 6. | | | | | | | | | | | | | | | | | |
| 7. | | | | | | | | | | | | | | | | | |
| 8. | | | | | | | | | | | | | | | | | |
| 9. | | | | | | | | | | | | | | | | | |
| 10. | | | | | | | | | | | | | | | | | |
| 11. | | | | | | | | | | | | | | | | | |
| 12. | | | | | | | | | | | | | | | | | |
| 13. | | | | | | | | | | | | | | | | | |
| 14. | | | | | | | | | | | | | | | | | |
| 15. | | | | | | | | | | | | | | | | | |

(note) Msp = Microscopist STLS = Senior TB laboratory Supervisor Con=Controller Ump = Umpire reader

Gd = Good

Pr = Poor

B = Too big

S = Too small

Tk = Too thick

Tn = Too thin

O = Over decolourization

U = Under decolourization

Comments / Suggestions by umpire reader

To make smear thicker and even. The Staining solution must be filtered before use.

Date

Analyzed by (with signature) _____

| | | | | | | |
|---|--|---|-----------------------------|---|----------------------|-------|
| Example 5 | National Tuberculosis Programme, Myanmar | | | | Form B.1 | |
| External Quality Assessment | | | | | | |
| Feedback Sheet (Bright Field Microscopy) | | | | | | |
| Microscopy Center: | Dagon Myo Thit (South) | | Month/ Quarter/ Year: _____ | | | |
| Smear Reading | | | | | | |
| Result by Controller | Result by Microscopist | | | | | Total |
| | Neg | 1-9 AFB/ 100f | 1+ | 2+ | 3+ | |
| Neg | 5 | LF (+) | HF (+) | HF (+) | HF (+) | 5 |
| 1-9 AFB/ 100f | LF (-) 1 | | | QE | QE | 1 |
| 1+ | HF (-) | | | | QE | 0 |
| 2+ | HF (-) | QE | | | | 0 |
| 3+ | HF (-) | QE | QE | | | 0 |
| Total | 6 | 0 | | 0 | 0 | 6 |
| Classification of errors | | Number | No. of slide discussed | | | |
| Major Error | HF (+) | 0 | | | | |
| | HF (-) | 0 | | | | |
| Minor Error | LF (+) | 0 | | | | |
| | LF (-) | 1 | | | | |
| | QE | 0 | | | | |
| Total No. of errors | | 1 | | | | |
| Smear Preparation (Total number of slides rechecked = 6) | | | | | | |
| | Good | | Poor | | | |
| | no. | % | no. | % | | |
| Specimen Quality | 6 | 100 | | | | |
| Staining | 6 | 100 | | | O (%) U (%) | |
| Cleanliness | 6 | 100 | | | | |
| Thickness | 5 | 83 | 1 | 17 | Tk (%) Tn (17%) | |
| Size | 5 | 83 | 1 | 17 | S (17%) B (%) | |
| Evenness | 5 | 83 | 1 | 17 | | |
| Good = acceptable Tk = Too thick | | O = Over decolourization Tn = Too thin | | U = Under decolourization S = Too small B = Too big | | |
| Comments for Improvement: | | | | | | |
| Smear size should be 2x3cm and thickness should be thick enough to read printed words from newspaper kept behind the slide. | | | | | | |
| Date report submitted: _____ | | | Report by: _____ | | | |

| | | | | | | |
|---|--|--------------------------|------------------------|--------------------------------|------------------------|-------|
| Example 6 | National Tuberculosis Programme, Myanmar | | | | Form B.2 | |
| External Quality Assessment | | | | | | |
| Feedback Sheet (Fluorescence Microscopy) | | | | | | |
| Microscopy Center: | Dagon Myo Thit (South) | | | Month/ Quarter/ Year: | | |
| Smear Reading | | | | | | |
| Result by Controller | Result by Microscopist | | | | | Total |
| | Neg | 5-49 AFB/ 20 f | 1+ | 2+ | 3+ | |
| Neg | 5 | LF (+) | HF (+) | HF (+) | HF (+) | 5 |
| 5-49 AFB/ 20 f | LF (-)1 | | | QE | QE | 1 |
| 1+ | HF (-) | | | | QE | 0 |
| 2+ | HF (-) | QE | | | | 0 |
| 3+ | HF (-) | QE | QE | | | 0 |
| Total | 6 | 0 | 0 | 0 | 0 | 6 |
| Classification of errors | | Number | No. of slide discussed | | | |
| Major Error | HF (+) | 0 | | | | |
| | HF (-) | 0 | | | | |
| Minor Error | LF (+) | 0 | | | | |
| | LF (-) | 1 | | | | |
| | QE | 0 | | | | |
| Total No. of errors | | 1 | | | | |
| Smear Preparation (Total number of slides rechecked = 6) | | | | | | |
| | Good | | Poor | | | |
| | no. | % | no. | % | | |
| Specimen Quality | 6 | 100 | | | | |
| Staining | | | | | | |
| Cleanliness | 6 | 100 | | | | |
| Thickness | 5 | 83 | 1 | 17 | Tk (%) Tn (17 %) | |
| Size | 5 | 83 | 1 | 17 | S (17 %) B (%) | |
| Evenness | 5 | 83 | 1 | 17 | | |
| Good = acceptable | | O = Over decolourization | | U = Under decolourization | | |
| Tk = Too thick | | Tn = Too thin | | S = Too small B = Too big | | |
| Comments for Improvement: | | | | | | |
| Smear size should be 2x3cm and thickness should be thick enough to read printed words from newspaper kept behind the slide. | | | | | | |
| Date report submitted: | | | Report by: | | | |

| | | | | | | |
|---|--|---------------|---------------------------|-----------------------|------------------------|-------|
| Example 6 | National Tuberculosis Programme, Myanmar | | | | Form B.2 | |
| External Quality Assessment | | | | | | |
| Feedback Sheet (Fluorescence Microscopy) | | | | | | |
| Microscopy Center: | Dagon Myo Thit (South) | | | Month/ Quarter/ Year: | | |
| Smear Reading | | | | | | |
| Result by Controller | Result by Microscopist | | | | | Total |
| | Neg | 5-49 AFB/ 20f | 1+ | 2+ | 3+ | |
| Neg | 5 | LF (+) | HF (+) | HF (+) | HF (+) | 5 |
| 5-49 AFB/ 20 f | LF (-)1 | | | QE | QE | 1 |
| 1+ | HF (-) | | | | QE | 0 |
| 2+ | HF (-) | QE | | | | 0 |
| 3+ | HF (-) | QE | QE | | | 0 |
| Total | 6 | 0 | 0 | 0 | 0 | 6 |
| Classification of errors | | Number | No. of slide discussed | | | |
| Major Error | HF (+) | 0 | | | | |
| | HF (-) | 0 | | | | |
| Minor Error | LF (+) | 0 | | | | |
| | LF (-) | 1 | | | | |
| | QE | 0 | | | | |
| Total No. of errors | | 1 | | | | |
| Smear Preparation (Total number of slides rechecked = 6) | | | | | | |
| | Good | | Poor | | | |
| | no. | % | no. | % | | |
| Specimen Quality | 6 | 100 | | | | |
| Staining | | | | | | |
| Cleanliness | 6 | 100 | | | | |
| Thickness | 5 | 83 | 1 | 17 | Tk (%) Tn (17 %) | |
| Size | 5 | 83 | 1 | 17 | S (17 %) B (%) | |
| Evenness | 5 | 83 | 1 | 17 | | |
| Good = acceptable | O = Over decolourization | | U = Under decolourization | | | |
| Tk = Too thick | Tn = Too thin | | S = Too small | | B = Too big | |
| Comments for Improvement: | | | | | | |
| Smear size should be 2x3cm and thickness should be thick enough to read printed words from newspaper kept behind the slide. | | | | | | |
| Date report submitted: | | | | Report by: | | |

| National Tuberculosis Programme | | Form C |
|--|---|---|
| Supervision Check List for TB Laboratory | | |
| | | Date: |
| Name of Township: | | |
| | | <input type="checkbox"/> General Laboratory |
| | | <input type="checkbox"/> TB Laboratory |
| | | |
| Sr. No. | Questions | Answers |
| 1 | Interview with laboratory staff ●How many staff work in the laboratory? Any vacancy? | |
| | ●Have they received NTP training? When? | |
| | ●Do they have the NTP laboratory manual? | |
| 2 | Sputum Collection ● When do patients cough up the sputum specimens? | |
| | ●How many sputum specimens are collected from each presumptive TB? | |
| 3 | Smear request form ●How are smears requested and reported? | |
| | ●Is the NTP smear request form used? | |
| 4 | Sputum containers ●Are there adequate supplies? | |
| | ●Are they marked properly (laboratory number on the side) ? | |
| 5 | Laboratory register ●Is the NTP laboratory register used? | |
| | ●Is it filled completely? | |
| | ●Do negative presumptive TB have 2 negative smears? | |
| | ●Do positive cases have 1 positive smear? | |
| | ●Are positive results written in red? | |
| | ●How many smear (diagnosis and follow - up) were examined recently? | |
| | ●Do they put township TB register number in remark column of lab. register? | |
| 6 | Slides ● Are there adequate supplies? | |
| | ●Is the laboratory number marked on the slide properly? | |
| | ●Check some positive and negative smears are they smeared, stained and reported correctly? | |
| 7 | Reagents ●Are there sufficient quantities of reagents? | |
| | ●Are bottles label with the name,date of preparation and expiry ? | |

| Example | | National Tuberculosis Programme, Myanmar | | | | | | | | | | | | Form (1) | | | | |
|---|-------------------------|--|-------|-------|---------|-------|-------|-------|---------|-------|-------|-------|---------|-----------|-------|-------|---------|--------|
| | | Smear Slide Preparation by Microscopy Center | | | | | | | | | | | | | | | | |
| Microscopy Center: Dagon Myo Thit (South) | | | | | | | | | | | | | | Year: 2 5 | | | | |
| Month | | 1 | 2 | 3 | 1st Qtr | 4 | 5 | 6 | 2nd Qtr | 7 | 8 | 9 | 3rd Qtr | 10 | 11 | 12 | 4th Qtr | Annual |
| Slide no. for EQA | n | 6 | | | | | | | | | | | | | | | | |
| | % | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) |
| Specimen Quality | Good | 6 | | | | | | | | | | | | | | | | |
| | Poor | 100 | | | | | | | | | | | | | | | | |
| Staining | Good | 6 | | | | | | | | | | | | | | | | |
| | % | 100 | | | | | | | | | | | | | | | | |
| | O | | | | | | | | | | | | | | | | | |
| Cleanliness | U | | | | | | | | | | | | | | | | | |
| | Good | 6 | | | | | | | | | | | | | | | | |
| Thickness | % | 100 | | | | | | | | | | | | | | | | |
| | Good | 5 | | | | | | | | | | | | | | | | |
| | % | 83 | | | | | | | | | | | | | | | | |
| Size | Tk | | | | | | | | | | | | | | | | | |
| | Tn | 1 | | | | | | | | | | | | | | | | |
| | Good | 5 | | | | | | | | | | | | | | | | |
| Evenness | % | 83 | | | | | | | | | | | | | | | | |
| | S | 1 | | | | | | | | | | | | | | | | |
| | B | | | | | | | | | | | | | | | | | |
| Evenness | Good | 5 | | | | | | | | | | | | | | | | |
| | % | 83 | | | | | | | | | | | | | | | | |
| | Poor | 1 | | | | | | | | | | | | | | | | |
| | O: Over decolorization | | | | | | | | | | | | | | | | | |
| | U: Under decolorization | | | | | | | | | | | | | | | | | |
| | Tk: Too thick | | | | | | | | | | | | | | | | | |
| | Tn: Too thin | | | | | | | | | | | | | | | | | |
| | S: Too small | | | | | | | | | | | | | | | | | |
| | B: Too big | | | | | | | | | | | | | | | | | |

| Example | | National Tuberculosis Programme, Myanmar | | | | | | | | | | | | Form (2) | | | | | | | |
|--|-------|--|-------|---------|-------|-------|-------|---------|-------|-------|-------|---------|-------|---|-------|---------|--------|---|--|--|--|
| Smear Slide Reading by Microscopy Center | | | | | | | | | | | | | | | | | | | | | |
| Microscopy Center: Dagon Myo Thit (South) | | | | | | | | | | | | | | | | | | | | | |
| Month | 1 | 2 | 3 | 1st Qtr | 4 | 5 | 6 | 2nd Qtr | 7 | 8 | 9 | 3rd Qtr | 10 | 11 | 12 | 4th Qtr | Annual | | | | |
| Slide no. | 6 | | | | | | | | | | | | | | | | | | | | |
| for QA | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | (100) | | | | |
| (-) by Mx | 5 | | | | | | | | | | | | | | | | | | | | |
| (+) by Mx | 1 | | | | | | | | | | | | | | | | | | | | |
| Correct | 5 | | | | | | | | | | | | | | | | | | | | |
| HF (+) | 0 | | | | | | | | | | | | | | | | | | | | |
| HF (-) | 0 | | | | | | | | | | | | | | | | | | | | |
| LF (+) | 0 | | | | | | | | | | | | | | | | | | | | |
| LF (-) | 1 | | | | | | | | | | | | | | | | | | | | |
| QE | 0 | | | | | | | | | | | | | | | | | | | | |
| Total * n | 1 | | | | | | | | | | | | | | | | | | | | |
| Error % | 17% | () | () | () | () | () | () | () | () | () | () | () | () | () | () | () | () | | | | |
| HF (+) = High False Positive = Major Error | | | | | | | | | | | | | | LF (+) = Low False Positive = Minor Error | | | | QE = Quantification Error = Minor Error | | | |
| HF (-) = High False Negative = Major Error | | | | | | | | | | | | | | LF (-) = Low False Negative = Minor Error | | | | | | | |
| * Total error = Major error + Minor error | | | | | | | | | | | | | | n = number | | | | | | | |

| National Tuberculosis Programme, Myanmar | | | | | | | | | | Form (3) | |
|---|------------------------------|-----------------------------|--|-------|-------------|-------|-------------|-----|-------------------------|---|---|
| Example | | External Quality Assessment | | | | | | | | | |
| Smear Slide Reading (State/Region, QA Center) | | | | | | | | | | Month/ Quarter/ Year: | |
| State/ Region: <u>Yangon Region</u> | | | | | | | | | | | |
| Microscopy Center | | Slide for QA | Major Error | | Minor Error | | Major Error | | No. of slides discussed | | |
| | | | HF(+) | HF(-) | LF(+) | LF(-) | QE | (n) | | | % |
| 1 | Dagon Myo Thit (South) | 6 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 (15-100-1) | |
| 2 | Latha TB Dx Center | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 3 | Aung San, UTI | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 4 | Hlaingtharyar Health Center | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 5 | East District (Bahan) | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 6 | North Okkalapa Health Center | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 7 | Shwepyithar Health Center | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 8 | Dawbon Health Center | 6 | 0 | 1 | 0 | 0 | 0 | 1 | 17% | 1 (15-125-1) | |
| 9 | Thaketa Health Center | 6 | 0 | 3 | 0 | 0 | 0 | 3 | 50% | 3 (15-21-1), (15-45-2), (15-93-1) | |
| 10 | Thanlyin Health Center | 6 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | | |
| 11 | | | | | | | | | | | |
| 12 | | | | | | | | | | | |
| 13 | | | | | | | | | | | |
| 14 | | | | | | | | | | | |
| 15 | | | | | | | | | | | |
| 16 | | | | | | | | | | | |
| 17 | | | | | | | | | | | |
| 18 | | | | | | | | | | | |
| 19 | | | | | | | | | | | |
| 20 | | | | | | | | | | | |
| Total | | 60 | 0 | 4 | 0 | 1 | 0 | 4 | 6.7% | | |
| HF(+) = High False Positive = Major Error | | | LF(+) = Low False Positive = Minor Error | | | | | | | QE = Quantification Error = Minor Error | |
| HF(-) = High False Negative = Major Error | | | LF(-) = Low False Negative = Minor Error | | | | | | | | |

| Example | | National Tuberculosis Programme, Myanmar | | | | | | | | | | Form(4) | | | | | | |
|-------------------------------------|------------------------------|--|--------------------------|------|---------------|-----|--------------|------|-----------|------|------|------------------------|----------|----|----|------|------|--|
| | | External Quality Assessment | | | | | | | | | | | | | | | | |
| | | Smear Slide Preparation(State/Region, QA Center) | | | | | | | | | | | | | | | | |
| State/ Region: <u>Yangon Region</u> | | | | | | | | | | | | Month/ Quarter/ Year : | | | | | | |
| Microscopy Center | Slide for QA | | Specimen Qty | | Staining | | Cleanliness | | Thickness | | Size | | Evenness | | | | | |
| | | | Good | Poor | Good | O | U | Good | Poor | Good | Tk | Tn | Good | S | B | Good | Poor | |
| 1 | Dagon MyoThit (South) | 6 | n | 6 | | 6 | | | | 6 | | 1 | 5 | 1 | | 5 | 1 | |
| | | | % | 100 | | 100 | | | | 100 | | 17 | 83 | 17 | | 83 | 17 | |
| 2 | Latha Dx Center | 6 | n | 6 | | 6 | | | | 6 | | | 6 | | | 6 | | |
| | | | % | 100 | | 100 | | | | 100 | | | 100 | | | 100 | | |
| 3 | Aung San, UTI | 6 | n | 4 | 2 | 5 | | 1 | | 4 | | 2 | 6 | | | 6 | | |
| | | | % | 67 | 33 | 83 | | 17 | | 66 | | 34 | 100 | | | 100 | | |
| 4 | Hlaing Tharyar Health Center | 6 | n | 6 | | 6 | | | | 6 | | 2 | 4 | 1 | 1 | 4 | 2 | |
| | | | % | 100 | | 100 | | | | 100 | | 34 | 66 | 17 | 17 | 66 | 34 | |
| 5 | East District (Bahan) | 6 | n | 6 | | 6 | | | | 6 | | 2 | 6 | | | 6 | | |
| | | | % | 100 | | 100 | | | | 100 | | 34 | 100 | | | 100 | | |
| 6 | North Okkalapa Health Center | 6 | n | 6 | | 6 | | | | 6 | | | 4 | 2 | | 6 | | |
| | | | % | 100 | | 100 | | | | 100 | | | 66 | 34 | | 100 | | |
| 7 | Shwepyithar Health Cente | 6 | n | 6 | | 6 | | | | 5 | 1 | | 5 | 1 | | 5 | 1 | |
| | | | % | 100 | | 100 | | | | 83 | 17 | | 83 | 17 | | 83 | 17 | |
| 8 | Dawbon Health Center | 6 | n | 6 | | 6 | | | | 4 | | 2 | 6 | | | 5 | 1 | |
| | | | % | 100 | | 100 | | | | 67 | | 33 | 100 | | | 83 | 17 | |
| 9 | Thaketa Health Center | 6 | n | 6 | | 6 | | | | 5 | 1 | | 3 | 3 | | 6 | | |
| | | | % | 100 | | 100 | | | | 83 | 17 | | 50 | 50 | | 100 | | |
| 10 | Thanlyin Health Center | 6 | n | 6 | | 6 | | | | 4 | | 2 | 48 | 8 | 4 | 0 | 6 | |
| | | | % | 100 | | 100 | | | | 67 | | 33 | 80 | 13 | 7 | 0 | 100 | |
| | Total | 60 | n | 58 | 2 | 59 | | 1 | | 47 | 2 | 11 | 48 | 8 | 4 | 49 | 11 | |
| | | | % | 97 | 3 | 98 | | 2 | | 78 | 3 | 19 | 80 | 13 | 7 | 82 | 18 | |
| | | | O : Over decolourization | | Tk: Too thick | | S: Too small | | | | | | | | | | | |
| | | | U: Under decolourization | | Tn: Too thin | | B: Too big | | | | | | | | | | | |

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