QUALITY ASSURANCE IN SPUTUM SMEAR MICROSCOPY

PRL GUIDELINES

August, 2007

Provincial Tuberculosis Control Programme Punjab
Provincial Reference Laboratory Punjab

Association for Social Development (ASD) Pakistan

Nuffield Institute for Health (NIH) UK

CONTRIBUTORS

TB Control Programme	
1. Dr. Darakshan Badar	Manager, Provincial Tuberculosis Control Programme Punjab
2. Dr. Zarfishan Tahir	Manager, Provincial Reference Laboratory Punjab
Association for Social Development Pakistan	
1. Dr Muhammad Amir Khan	Chairman
2. Dr. Nayyar Ghias	Central Coordinator
3. Dr. Jaffar Saleem	Central Coordinator
4. Dr Nauman Safdar	Lead Professional
5. Mr. Abdul Rauf Qadir	IT Specialist
Systems Development Experts	
1. Dr. Maqsood Ahmad	Former Dean, Institute of Public Health Lahore
2. Dr. Muhammad Arif Munir	Former Director, Directorate of Malaria Control Islamabad
3. Dr John D Walley	Nuffield Centre for International Health and Development, University of Leeds UK

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Section-A	INTRODUCTION TO QUALITY ASSURANCE OF LABORATORY SERVICES

1. Quality of Sputum Smear Microscopy in TB Control

Early diagnosis and effective treatment is the key element of the DOTS strategy package. Failure to detect persons with TB can lead to continued spread of infection in the community. The WHO strategy for tuberculosis control (DOTS) relies on a network of laboratories that provide acid-fast bacilli (AFB) sputum smear microscopy. The AFB result determines the treatment and outcome of an individual TB patient. If the laboratory diagnosis is unreliable, all other activities of the TB control programme are affected. Therefore, quality assurance of laboratory services, including AFB sputum smear microscopy, is essential. The quality of sputum smear microscopy services can only be assured through staff commitment at facility, district, provincial and national levels.

2. External Quality Assurance (EQA)

The National Tuberculosis Programme (NTP) requires the AFB testing laboratories to be managed by a system of external quality assurance (EQA) and quality improvement that meets international standards.

2.1 Purpose of EQA

External quality assurance is an approach in which the performance of facility staff is assessed and supported on regular basis by expertise from outside the facility. The purpose of EQA at a diagnostic center is to improve the quality and the trust-worthiness of the smear results through:

- Availability and quality of laboratory inputs including reagents, supplies, print materials, and microscope.
- Continued skill and capacity enhancement for performing the laboratory related tasks e.g. smear preparation and examination, storage and disposal of slides, and recording and reporting of smear results.

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 diagnoses**.** It is also a very important tool for communication with and motivation of laboratory staff that may otherwise feel isolated in their work.

2.2 Methods Used in EQA

There are three methods that can be combined to evaluate laboratory performance:

On-Site Evaluation

The observation of laboratory arrangements and working under actual conditions include: quality and functioning of equipment; adequacy and quality of reagents and supplies; slide storage; record keeping; and laboratory safety. Documentation of the onsite evaluation process, on standardized formats, helps to monitor the changes in laboratory arrangements and practices over a period.

Blinded Rechecking

The DLS, during the monthly visit, would recheck a random sample of slides prepared and examined at the diagnostic center during the month under review. The method for selecting,

rechecking, recording and cross validating the results is described in the respective sections of DLS Guidelines.

Panel Testing

In this method, the laboratory person is provided a set of stained and/ or unstained slides for reading, interpreting and reporting the results. This method tests the technician's ability to stain and/or read smears, and is not a useful mean to assess routine laboratory performance. In TB control programme, the provincial reference laboratory would periodically administer the panel testing to assess staff skills.

2.3 Organizational Arrangements for EQA

The EQA at a facility is implemented through collaborative efforts of facility, district and provincial level staff.

2.3.1 Facility Level

Two main staff members involved in EQA are Medical Officer (MO) and laboratory staff.

M.O In-charge**:**

- Selects a sample of slides, as per programme guidelines, for reexamination by the DLS.
- Enters the facility results (from TB04) into EQA Form, and participate in comparing these with the DLS reexamination results.
- Discuss the EQA findings, and facilitate the process to address the gaps in laboratory arrangements and practices.

Laboratory staff**:**

- Maintains the laboratory register and stores all slides for re-checking.
- Shares the technical and logistic issues constraining his AFB testing work.
- Complies with the instructions of the District Laboratory Supervisor and M.O In-charge for improved quality of AFB testing.

2.3.2 District Level

Two main district level staff members involved in EQA are District Laboratory Supervisor (DLS) and District TB Coordinator (DTC).

DLS:

An enabled District Laboratory Supervisor (DLS) visits each TB diagnostic center, on monthly basis. During visit, the DLS performs EQA mainly through the onsite evaluation and blinded rechecking of a sample of TB slides. The assessment is followed by onsite interaction between the facility staff and the DLS for better understanding and action planning. The DLS is responsible to:

- Plan, conduct, document and report monthly supervisory visits to each diagnostic center in the district.

- Carry out and documenting the onsite evaluation and providing support to plan/address the material and ability gaps.
- Carry out and document the onsite blinded rechecking of sample slides, as per programme guidelines. This also includes providing feedback to health facility staff i.e. facility in-charge as well as laboratory staff.
- Maintain communication with the provincial reference laboratory (PRL) including sending them the discordant slides, facilitating their examining a sample of concordant slides (during supervisory visit of the district), and participating in quarterly interaction with them (i.e. PRL staff).

The operational details for DLS planning, carrying out, documenting and following-up the EQA activities in a district are described in DLS Guidelines.

District TB Coordinator

- Supervise (administrative) and support the DLS work in the district including approving and monitoring his visit plans, facilitating the availability of laboratory reagents and supplies.
- Contribute in the laboratory related discussions held during the facility review/planning meeting.
- Comment on the DLS performance presented in the quarterly intra-district meeting.
- Facilitate communication with provincial reference laboratory including:
    - Ensure the discordant slides are sent and feedback is received in-time;
    - DLS attends the quarterly meeting at PRL; and
    - PRL staff quarterly monitoring visit to the district is facilitated.

2.3.3 Province Level

A strengthened provincial level laboratory (PRL) setup provides the training and supervision support to the district laboratory supervisors. The responsibilities include:

- Design and conduct the training of District Laboratory Supervisors (DLS) from all districts in the province.
- Reexamine the discordant slides received from the districts, keep record and provide in-time feedback to the districts.
- Develop and conduct the interaction and build capacity of DLS, when they come for quarterly monitoring event PTP.
- Plan and conduct quarterly supervisory visits to all the participating districts.
- Communicate with National Reference Laboratory for EQA work in province.

Section-B	QUARTERLY VIST OF PRL STAFF TO DISTRICT

Supervision is the process of helping the staff to improve their performance. Supervisory visits give staff and his supervisor to share and better understand the situation, and motivate the staff to perform at their best. During these visits, the correct performance is reinforced and deviation in practice is identified and corrected. The corrective measures are discussed and agreed with the DLS and District TB Coordinator (where needed). Thorough planning and preparation helps making the PRL staff visit more productive and efficient. Following guidelines will in making the visit more effective.

1. Prepare Quarterly Plan

- Prepare quarterly district visit plan, on the format given below. The quarterly plan of the PRL staff needs to take into account other facility monitoring activities being planned by the District TB Coordinator during the month.
- Communicate the plan to DLSs with a copy to DTC at the beginning of each quarter.

PRL Staff Quarterly Visit Plan

Date	District	Remarks

Notes on filling the table:
Date - the date on which the facility is to be visited
District - the district to be visited on that date
Remarks - Note any particular observation/action for the district, in light of observations/discussions during the last visit.

2. Assess the EQA Centre

Use the EQA Form-3, Section-1 to record the number of days the laboratory remained non-functional, reasons for non functioning, onsite actions taken and actions required at district health office/coordinator levels.

EQA Form-3
Section-1: Laboratory Functioning

No. of days Lab. Remained non functional	Reasons	Actions already taken/ Onsite actions	Actions required/agreed

3. Assess Laboratory Supplies and Materials at EQA Centre

- Use the EQA Form-3, Section-2A to check the laboratory supplies situation.

EQA Form-3
Section-2A: Estimated Requirement of Laboratory Supplies at EQA Centre (6 months)

Item	Diagnostic Centre Requirement - 6 month (A)	District Requirement						
		Quantity of chemical/ reagent	Up to 10 Labs.		11 to 15 Labs.		16 & above Labs	
Reagents			**# liters of prepared solution (B)** (A x # DCs in a district)	**Quantity of chemical/ reagent**	**# liters of prepared solution (B)** (A x # DCs in a district)	**Quantity of chemical/ reagent**	**# liters of prepared solution (B)** (A x # DCs in a district)	**Quantity of chemical/ reagent**
1. 25% H_2SO_4 (250 ml acid for 1 liter solution)	5 liters (1 liter pack)	(B / 4 litres)	5x10 = 50 liters	50/4 = 13 liters	5x15 = 75 liters	75/4 = 19 liters	5x20 = 100 liters	100/4 = 25 liters
2. 1% Carbol fuchsin (-10 gm basic fuchsin powder - 100 ml ethanol -50 gm Phenol crystals for I litre solution)*	5 liters (1 liter pack)	(B x 10 gms)	5x10 = 50 liters	50 x 10 = 500 gms	5x15 = 75 liters	75 x 10 = 750 gms	5x20 = 100 liters	100 x 10 = 1000 gms
		(B x 100 ml)		50x 100 =5000 ml		75 x 100 =7500 ml		100 x 100 = 10000 ml
		(B x 5 0gms)		50 x 50 = 250 0gms		75 x 5 0 = 3750 gms		100 x 50 = 5000 gms
3. 0.3% Methylene blue (3gm powder for I litre solution)*	5 liters (1 liter pack)	(B x 3 gms)	5x10 = 50 liters	50 x 3 = 150 liters	5x15 = 75 liters	75 x 3 = 225 gms	5x20 = 100 liters	100 x 3 = 300 gms
4. Immersion oil (500ml bottle)	1 bottle		10 bottles		15 bottles		20 bottles	
5. Xylene or Toluene (250 ml bottle)	1 bottle		10 bottles		15 bottles		20 bottles	
6. Methylated spirit (1 litre bottle)	1 bottle		10 bottles		15 bottles		20 bottles	
General Supplies								
1. Glass slides	14 packs (72 each)		140 packs		210 packs		280 packs	
2. Sputum containers	1000		10000		15000		20000	
3. Slide storing boxes (100 slides)	2 boxes		20 boxes		30 boxes		40 boxes	
4. TB laboratory register (TB04)	One per diagnostic centre. Replenished only		10		15		20	
5. Wire loop	1		10		15		20	
6. Diamond pen	1		10		15		20	

7. Functioning microscope	1		10	15	20

* In ASD project, repacked in 50 gm packs for distribution to the district. DLS prepares/distribute stain to facilities

- Fill the EQA Form-3, Section-2B

– For each item, fill the quantity of available stock in the "Stock available" column.
  - Calculate the amount of materials to be arranged and fill in the column "Shortfall"
  - Agree on how to get the "Shortfall" materials and write in the Comments/Actions column.

EQA Form-3
Section-2B: Laboratory Inputs Replenishment

Item	Minimal Stock Level of respective District	Stock available	Shortfall	Comments/Actions
25% H_2SO_4				
1% Carbolfuchsin				
0.3% Methylene blue				
Immersion Oil				
Xylene or Toluene				
Methylated Spirit				
Glass Slides				
Sputum Containers				
TB04				
Slide Storing Boxes				
Wire Loop				
Diamond Pen				
Functioning Microscope				

4. Observe Microscope Maintenance, Slide Storage and Waste Disposal

Check and record in EQA Form-3, Section-3.

4.1 Microscope maintenance

- Check for cleanliness and proper functioning of microscope. The use of microscope is given in Laboratory Training Course in Session-VI. The maintenance of microscope and troubleshooting checklist/guide is given in DLS Guidelines Appendix-1.

4.2 Slide Storage

- Check that all slides are stored by the DLS in the provided slide boxes.
- Check that oil has been removed from the examined slides before storage by the DLS.
- Check that slides are stored in boxes that do not allow the slides to touch each other (e.g., do not stack or press slides together) and boxes are placed away from direct sunlight.
- Check that slides are stored health facility wise

4.3 Observe Slides Disposal

This is very important that laboratory personnel follow the NTP protocols for safe disposal of slides.

- Check that the used glass slides are initially disinfected, by boiling in the water for about 20 – 30 minutes or by putting in phenol. Then these disinfected slides are buried in the ground.

All cross-examined slides kept with DLS are discarded only when PRL staff asks the DLS to do so, during their supervisory visit to the district.

EQA Form-3
Section-3: Microscope maintenance, Slide storage and Waste disposal

Characteristic	Acceptable		Action/Comments
	Yes	No	
Microscope cleanliness			
Microscope functioning			
Slide Storage			
Disposal of used slides			

5. Assess Quality of Reagents

The district health office will arrange the laboratory supplies through PTP inputs as well as their own sources and will supply these supplies and materials for DOTS implementation through a network of diagnostic centers.

Fidelis Districts
ASD will arrange a buffer stock to address gaps and interruptions in the district supplies. The ASD materials will mainly be procured centrally, in consultation with PRL, and stored and distributed through the district health office. However, Regional Coordinators will also do local purchase of minor items (such as sputum containers, slides etc.) to avoid delay in response to material gaps. Separate records of ASD supplies will be maintained for FIDELIS audit purposes.

Quality control is necessary to ensure that the stains (especially carbolfuchsin) work well, and that they do not contain contamination of AFB.

☞ During district visit check;

- Whether the stain-preparing laboratory has prepared two positive smears for the quality of stains and two negative smears for checking the AFB contamination.
- Batches of stains have been identified by name of reagent and preparation date (as on the bottle labels).
- Stains are not outdated
- Stains are kept appropriately and away from sunlight
- Record of prepared stains using the following table (provided in DLS guidelines) is kept regularly

Lot No.	Date of Preparation	Result of stain with control slide		Remarks
		(+) Slide	(-) Slide	

6. Assess Reexamined Slides

During the health facility visit the PRL staff will assess a sample of the slides reexamined by the DLS. The programme recommends the following process for selecting and assessing the reexamined slides by the PRL staff.

6.1 Sampling

Select 10 slides randomly from the slides of last quarter for assessment of reexamined slides.

- Select 5 centers randomly
- Select 2 slides randomly from each centre

6.2 Smear Assessment

Check the selected sample of slides for the following seven smear characteristics (and note the findings in Section-1 of EQA Form-3).

Specimen Quality: The presence of dust cells (macrophages) and white blood cells (WBCs) in the smear is an evidence that specimen is sputum not saliva. (Note: Look for WBCs in X 100, and dust cells in X 1,000).

Size: The smear size of approximately 1cm x 2cm is considered acceptable.

Thickness: Acceptable thickness of smear (unstained) can be checked by looking at printed letters through the smear, holding the smeared glass slide 4 – 5cm over a printed-paper. In normal smear thickness letters are blurred but readable. If letters cannot be read, it is too thick. On the other hand, clear print indicates thin smear.
A stained slide can be checked for appropriate thickness by observing it under the microscope; if the entire depth of the smear can be focused sharply in each field, its thickness is acceptable.

Evenness: Sputum should be spread evenly on the glass slide: not too thick not too thin.

Slide Labeling: The slides should be marked with a diamond pen and writing must be readable. The guidelines for marking/labeling of slides must be followed i.e. laboratory number followed by sequence number e.g. 100-A,B,C (for diagnosis) or F (for follow-up)

Staining: AFB should be stained in red or dark pink. AFB and background must be clearly distinguished. If Ziehls carbol fuchsin is retained in the stained smear ,it must be evaluated as poorly decolorized.

Smear Cleanliness: Stained smear must be free from stain deposits, dirt, debris, fuchsin crystals produced by overheating during staining.

Overall quality of smear is determined on the basis of all the sample slides examined for the selected seven main characteristics. The observations on each slide is recorded in section-3 of the EQA Form-3, column 'PRL' by putting codes "A" for acceptable and "NA" for not acceptable. The overall quality on each of seven characteristics is declared acceptable if only two or less slides (i.e. less than 25%) are judged as not acceptable. The overall quality remarks are recorded in the last row of the table in section 1 of the EQA-3.

Transfer the DLS results from Section-5 of EQA Form-1 in column DLS of the section-4, EQA Form-3.

EQA Form-3
Section-4: Smear Assessment of Selected Slides

Lab Serial No.	**1.Specimen Quality**		**2.Size**		**3.Thickness**		**4.Evenness**		**5.Labeling**		**6.Slide Staining**		**7.Smear Cleanness**	
	DLS	**PRL**	**DLS**	**PRL**	**DLS**	**PRL**	**DLS**	**PRL**	**DLS**	**PRL**	**DLS**	**PRL**	**DLS**	**PRL**
Total Agr														
% Agr														
Remarks***														

Key:
*A - Acceptable,
**NA - Not Acceptable,
*** Remarks – Gives overall performance of the characteristic under consideration. If for any characte three or more slides are found not in agreement with DLS result then overall performance on that characteristic is requires guidance and correction.

If performance on any of the characteristics from 1-5 is found 'Not in Agreement' ask the DLS to read Session IV, Smear Preparation from the Laboratory Training Course Module.

If performance on any of the characteristics from 6-7 is found 'Not in Agreement' ask the DLS to read Session V, ZN Staining from Laboratory Training Course Module.

6.3 Quality of results of reexamined slides

- Sample 10 slides
- Assess the results of the selected sample slides in the DLS laboratory. This onsite assessment provides an opportunity of onsite feedback and skill enhancement of the DLS. Record the assessed results in section-5 of EQA Form-3 in column; PRL Result.
- Transfer the DLS results from section-6 of EQA Form-1 in column 'DLS Result'
- Write a comparison in the 'Comparison' column

EQA Form-3
Section-5: Slide Result Assessment by PRL Staff

S. No	Lab. Serial No.	Reexamine Result	Diagnostic Center Result	Comparison						Remarks
				AG	HFP	LFP	HFN	LFN	QE	
1.										
2.										
3.										
4.										
5.										
6.										
7.										
8.										
9.										
10.										
Summary results										

Notes on Section-5 columns:

- *Lab. Serial Number* as recorded on each selected slide. This is filled by PRL staff for the sampled slides
- *PRL Result* refers to the smear results of each selected slide, as assessed by the second controller (PRL).
- *DLS Result* refers to the smear result of each selected slide by the DLS, as recorded in EQA Form-1, Section-6.
- *The* results recorded in the two result columns are compared and accordingly recorded in the comparison part of the table. The PRL staff compares the results and records by putting a "tick " mark in the relevant column.
  - Agreement (AG): refers to that smear results of DLS found concordant with PRL result.
  - *False Positive (FP):* refers to that smear positive results (given by the DLS), which were found smear negative by the second controller (PRL). False positives can either be high or low false positive.

a. *High False Positive (HFP): refers to a negative smear misread as 1+ to 3+ (based on IUATLD/ WHO recommended grading of sputum smear microscopy results). This is a major error.*

b. *Low False Positive (LFP): refers to negative smear that is misread as a scanty (1-9 AFB/100 fields) positive. It is a minor error.*

- *False Negative (FN):* refers to that smear negative results (given by the DLS), which were found smear positive by the second controller (PRL). False negatives can either be high or low false negatives.

  a. *High False Negative (HFN):* refers to 1+ to 3+ positive smear that is misread as negative. This is a major error.

  b. *Low False Negative (LFN):* refers to scanty (1-9 AFB / 100 fields) positive smear that is misread as negative. It is a minor error.

- *Quantification Error (QE* : Write down the *number of results with Quantification Error (QE) i.e.* grading difference (more than 2 degrees) but considered as agreed. (I.e. recorded under result agreement). This data could be extracted from EQA Form-1 Sectio-6: by comparing columns 'Reexamine Result' and 'Diagnostic Center Result'.

- *Summary results:* Gives the count of "tick marks" in each column.
- *Remarks:* PRL staff records the reasons for difference in results and agreed actions

➢ Discuss the false positive and false negative results with the DLS and take measures to address the gaps in his/her knowledge, skills and practices. Use the following guidelines for discussion and corrective actions.

Table 1

Sr. No.	Pattern of errors	Possible causes	Suggested investigation steps
1	False negative (FN)	Defective microscope/poor light.	Check microscope performance on-site (repair /replace).
		Insufficient time spent in scanning smear, incorrect microscopy technique	Refresher course for technician
		Poor stains.	Check stains /prepare new staining reagents.
		Staining problems (pale AFB, insufficient contrast in background), insufficient heating /staining time, very thick smears.	Refresher course for technician.
		Gross neglect, overworked, lack of motivation	Exclude other causes, motivate technician.
2	False positive (FP)	Administrative error	Compare lab-register and verify correct slide number and result. Exclude causes of more frequent FP, untrained or inexperienced lab staff.
		Poor registration routine	Check accuracy of lab-register and other record keeping
		Staining problems/Fading of AFB	Check stains and staining procedure.

		since original report. Artifact (e.g. stain deposits or crystals) incorrectly interpreted as AFB. AFB carried over in immersion oil or from a previous positive smear.	Re-stain all discordant slides (FP & FN) and re-examine. Refresher course for technician
		Defective microscope.	Check microscope performance on-site (repair /replace).
3.	Quantification error.	Lack of understanding of scoring system. Poor stains/staining.	. Refresher course for technician
		Incorrect microscopy technique. Defective microscope.	On-site check of microscope performance.

7. Review with DTC/EDO

- Fill the EQA Form-3, Section-6 and discuss it with EDO.

EQA Form-3
Section-6: Review with EDO

District	Problems	Agreed Actions	Progress on previous actions
Signature:_____ PRL Staff		Signature: _____ DTC/EDO	

8. Communication with PTP

- Consolidate the EQA Form-3, Section-6 all the districts in one form and send a copy to the Provincial TB Control Program.

Section-C	QUARTERLY PROVINCIAL EQA MONITORING EVENT

1. Aims and Objectives:

The **aim** is to improve the sputum smear microscopy across the province. The **purpose** is to improve technical and management support to the districts through a provincial level event. This will build on district level monitoring activities, as well as contribute to the national level monitoring activities. The objectives are:

- To review the External Quality Assurance (EQA) in terms of inputs, outputs and quality of sputum smear microscopy.
- To identify gaps in terms of human and material resources and agree on actions required.
- Capacity building of DLSs on specific issues and developments

2. Outputs

The outputs of the inter-district review meeting include:

- The EQA implementation of sputum smear microscopy reviewed and progress, gaps and agreed actions recorded for each district.
- Summary of district EQA indicators for the whole province prepared.
- Capacity of DLSs build

3. Preparations for the Meeting:

- The province arranges the one-day meeting, at a date and venue agreed in consultation with the districts and national TB control programme. DLSs from all the districts attend the meeting. The province arranges a venue with room for about 20 persons.
- The province arranges a venue with rooms for two or more groups of about 10 - 15 persons each, so as to enable active participation, depending on the provincial facilitators available. Audio-visual equipment (i.e. transparency projector) is required in each room, with a computer technician to assist participants in compiling/finalizing their presentations.
- The PTP Manager is overall supervisor of the quarterly inter-district EQA review meeting. The PRL staff facilitates meeting.
- The Provincial TB Control Programme arranges the venue, projector, transparencies, calculator and logistic arrangements e.g. accommodation, local travel, refreshments.

4. Components of the Event

The event will have two components; Presentation by the DLS and Group Work for identification of problems and agreement on solutions.

4.1 Presentation by the DLS

The DLS will prepare a presentation for the meeting and on the basis of previous completed quarter. The presentation will comprise of two slides:

Slide-1: Summary of Inputs and Outputs
Slide-2: Smear Assessment of Selected Slides

The DLS will use the format given on page15-16 for his presentation and will use the following guidelines for preparing the slides:

A. INPUTS
No. Diagnostic Centers:
Write the # of DCs visited in the quarter (Previous completed)

Resource Gaps at DCs

Materials: Enter the # of DCs with gaps in Lab materials. This information can be extracted from EQA Form-1, Section-2.

Staff: Write down the # of DCs without trained Lab. Staff. This information can be extracted from EQA Form-1, Section-2 last row 'Trained Lab Staff".

Resource Gaps at District Level

Trained DLS: Enter in this column 'Available' if the DLS is available and trained and 'Not available' if the DLS is either not available or is not trained

Mobility: Enter 'Yes' if the motorcycle is available and in functioning state and 'No' if the motorcycle is not-available or is not in a functioning state

Apparatus: Enter 'Available' if the stain preparation apparatus is available and 'Not-available' if not available (indicate the items not available)

Others: Record any other resource gap.

B. OUTPUTS
Av. # visits/DC

- Calculate the average # of visits by the DLS to DCs in the quarter using the formula; Average # of visits/ DC = Total # of visits /# of DCs
- Enter the calculation in this column

Av. # slides examined/Suspect
Take this figure from EQA Form-1, Section-3, and column ‘Statistic’ row 1.

SPR
Take this figure from EQA Form-1, Section-3, and column ‘Statistic’ row 3

Quarterly Slide Vol.
Take this figure from EQA Form-1, Section-3, and column ‘Statistic’ row 4

# of slides examined
Take this figure from EQA Form-2, Section-1, and column ‘#Total Slides reexamined’ last row.

#discordant slide
Take this figure from EQA Form-1, Section-6, and column ‘Comparison’. Add up the summary results of sub-columns HFP,LFP, HFN and LFN**.**

Provincial Level EQA System Monitoring Meeting
DLS Presentation

District _____
Quarter _____

A. INPUTS

No. Diagnostic Centers	Resource Gaps at DCs		Resource Gaps at District Level			
	Materials	Staff	Trained DLS	Mobility	Apparatus	Others

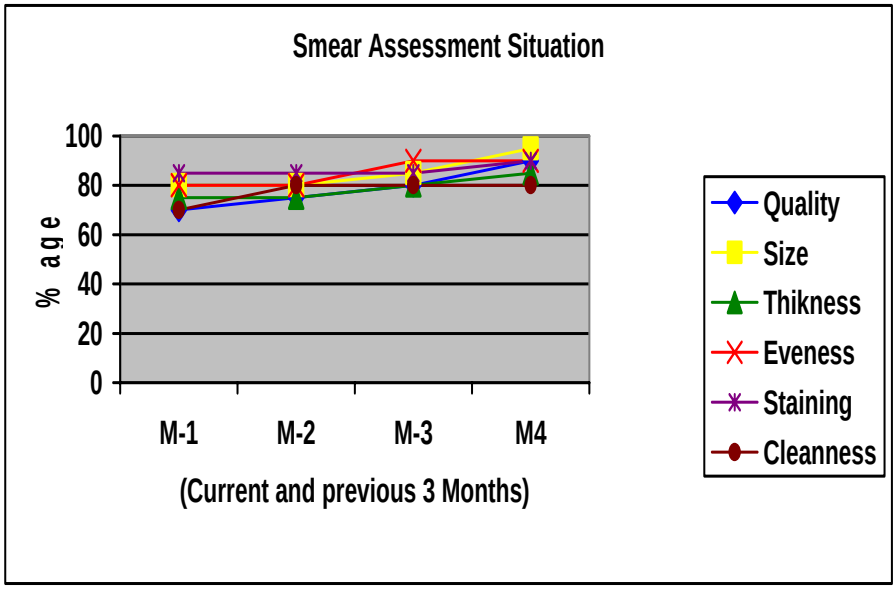
B. OUTPUTS

Av. # visits/DC*	Av.# slides examined /Suspect	SPR	Quarterly Slide Vol.	# of slides examined	#discordant slides

* Average # of visits/ DC = Total # of visits /# of DCs

C. SMEAR ASSESSMENT OF SELECTED SLIDES

The DLS will prepare the following graph showing quality of smear in the last quarter.



Notes for graph preparation

Graph Line Color	X – Axis	Y – Axis (% from EQA Form-2, Section-1)
Blue	Previous Four Months	Quality
Yellow		Size
Green		Thickness
Bright Red		Evenness
Violet		Staining
Dark Red		Cleanness

4.2 Group Work

A group work will be conducted facilitated by the PRL staff for identification of problems and agreement on solutions. Following format will be used:

Problems	Agreed Actions		Responsibility	Timing	Follow-up of last meeting
	Already Taken	To be Taken			

Section-D	Communication with National Reference Laboratory

Fill-up online NRL forms on quarterly basis:

- District QA Entry Form
- Lab Performance Data

Use the following guidelines for filling up these forms.

District QA Entry Form

Name of diagnostic Center:
Write the name and type (DHQ, THQ, and RHC) of the diagnostic center in this column.

Number of Patients Examined:

These three statistic are taken from the TB04 column "Reason for examination"

- Column – Total: Fill the next two columns first. Then add the figures in the next two columns to get the total number of patients examined (see below).
- Column – Suspect: Count the number of suspects examined for diagnosis (from TB04), and record the number in this column.
- Column – Follow-up: Count the number of patients examined for follow-up (from TB04), and record the number in this column.

Number of suspects with the following smears examined:

From TB04: Identify all the suspects examined (i.e. for diagnosis) during the period as recorded in "Reasons for examination". For each of the suspect examined count the number of smears examined as recorded in "Results of specimens". According to the number of smears examined, each suspect is recorded in one of the three cells by putting a tally mark. Patients from each page of the TB04 are recorded in a separate row of the table below.

Page (TB04)	Number of smears examined		
	One smear	Two smears	Three smears

Total number of tally marks in column "one smear" of the above table are counted and recorded in the column labeled "one" in the laboratory performance data sheet.

Total number of tally marks in column "two smears" of the above table are counted and recorded in the column labeled "two" in the laboratory performance data sheet.

Total number of tally marks in column "three smears" of the above table are counted and recorded in the column labeled "three" in the laboratory performance data sheet.

Total number of Diagnostic smears examined:

- Multiply the number entered in column 'One' with 1
- Multiply the number entered in column 'Two' with 2
- Multiply the number entered in column 'Three' with 3
- Add up three statistics and enter the total number in this column

Number of suspect with following +ve Smear:

From TB04: Identify all the suspects examined (i.e. for diagnosis) during the period as recorded in "Reasons for examination". For each of the suspect examined count the number of positive smears examined as recorded in "Results of specimens". According to the number of positive smears examined, each suspect is recorded in one of the three cells by putting a tally mark. Patients from each page of the TB04 are recorded in a separate row of the table below.

Page (TB04)	Number of smears examined		
	One +smear	Two + smears	Three + smears

Total number of tally marks in column "one +smear" of the above table are counted and recorded in the column labeled "one" in the laboratory performance data sheet.

Total number of tally marks in column "two + smears" of the above table are counted and recorded in the column labeled "two" in the laboratory performance data sheet.

Total number of tally marks in column "three + smears" of the above table are counted and recorded in the column labeled "three" in the laboratory performance data sheet.

Total # of +ve diagnostic smear:

- Multiply the number entered in column 'One' with 1
- Multiply the number entered in column 'Two' with 2
- Multiply the number entered in column 'Three' with 3
- Add up three calculations and enter in this column

Follow-up Examination

Take the number entered in column 'Number of patients examined' sub column 'Follow-up and enter in 'Total Smear'.
Count the follow-up cases with +ve smears from TB04 column 'Results of specimens' and enter the count in column '+ve smear'

Total # of +ve Suspects:

Add up the entries in sub columns 'One, Two, Three' of columns '# of suspects with Following Positive smears' and enter the added number in this column.
Smear Positivity Rate (%):

Divide the figure entered in column 'Total # of positive diagnostic smears' with figures in column 'Total # of Diagnostic smears examined' and multiply with 100. Enter this calculated result in this column.

Smear examined / Suspect:

Divide the figure entered in column 'Total # of Diagnostic smears examined' with figures in column 'Number of Patients Examined' sub column 'Suspects' and enter this calculated result in this column.

QA Entry Form

Date:
Write down the date of preparing the report.

Functioning Diagnostic Centers
Enter the number of functioning diagnostic centers in the concerned district. The centers without a trained person or non availability of Lab. supplies would be considered non functional.

# of Diagnostic Centers checked:
Enter the total number of diagnostic center checked by DLS during his routine monthly visit. This information could be found from the filled EQA form-1.

# of Diagnostic Centers with major errors:
Enter the number of diagnostic centers with major errors found i.e. (HFP, HFN) in the district.

Laboratory:
In this column write down the name of the diagnostic centers checked in the district functional or non functional.

ANSV (Annual Smear Volume):
Take the reading from sub column 'Statistic" of EQA Form-1Section-3: Recording & Reporting and record in this column.

Smear Positivity Rate (SPR):
Record Smear Positivity Rate (SPR) in QA Entry Form, column 'SPR'. This information can be extracted from EQA Form-1 Section-3, column 'Statistic'

# of slides Collected:

Column 'Pos' (Positive):
In this column write down the total number of positive slides collected in previous quarter. This information could be extracted from EQA Form-1 Section-5: Smear Assessment of Selected Slides.

Column 'Scn, (Scanty):

In this column write down the total number of scanty positive slides collected in previous quarter. This information could be extracted from EQA Form-1 Section-5: Smear Assessment of Selected Slides.

Column 'Neg' (Negative):
In this column write down the total number of Negative slides collected in previous quarter. This information could be extracted from EQA Form-1 Section-5: Smear Assessment of Selected Slides. Period under review is previous completed month.

Column-Total':

Add up the entries in sub columns 'Pos, Scn, and Neg 'of columns '#of slides collected' of QA entry form and enter the added number in this column.

Slides correct:

Write down the number of *correct* slides which refer to those smear positive or smear negative results (given by the diagnostic center), which were found concordant (up to 2 degrees) on subsequent cross-examination by the first controller (DLS). Get this information from; EQA Form-1, Section-6, column comparison, sub-column "AG"

Errors:

- Column –HFN**:** Write down the number of *High False Negative (HFN)* smear results. It refers to 1+ to 3+ positive smears that were misread as negative. This data could be extracted from EQA Form-1 Sectio-6: column comparison, sub-column "HFN"
- Column – HFP: Write down the *number of High False Positive (HFP)* smear results. It refers to a negative smears misread as 1+ to 3+. This data could be extracted from EQA Form-1 Sectio-6: column comparison, sub-column "HFP"
- Column – LFN: Write down the *number of Low False Negative (LFN)* smear result. It refers to scanty (1-9 AFB / 100 fields) positive smear that is misread as negative. This data could be extracted from EQA Form-1 Sectio-6: column comparison, sub-column "LFN"
- Column – LFP**:** Write down the *number of Low False Positive (LFP) smear result. It refers to negative smear that is misread as a scanty (1-9 AFB/100 fields) positive.* This data could be extracted from EQA Form-1 Sectio-6: column comparison, sub-column "LFP"
- Column – QE: Write down the *number of results with Quantification Error (QE) i.e.* grading difference (more than 2 degrees) but considered as agreed. (I.e. recorded under result agreement). This data could be extracted from EQA Form-1 Sectio-6 sub column 'QE".
- Column –Total:
  In this column write down the total errors. Add entries of the columns HFN, HFP, LFN, LFP, QE and write down their sum in this column.

The following variables will automatically be calculated on data entry at PRL level. However for under standing purpose the method of calculation is described.

Column - Agg %(Agreement %)

Add up the entries of the sub column 'CS' of Column Errors,/ Total slides collectedX100

Mj E (Major Error):
Add entries in columns HFN and HFP and enter in this column

Mn E (Minor Error)
Add entries in columns LFP, LFP, QE and enter in this column

FPR% (False Positive Rate %)
Total Number of FP (H&L) x100 / (Total smear Pos& Scn)

FNR% (False Negative Rate %)
LFN+HFN x100 / Total Negative slides collected.

Sen % (Sensitivity %)
Total reported positive (reported positive i.e Pos + Scn) / Total (HFN) + Number of slides collected (Pos + Scn.) x 100

Spc % (Specificity %)

Lab Performance Data

				Diagnostic Examination (TB Suspects)								Follow up Examination				
Name of diagnostic centers	Number of patients Examined			# of suspects with following smear examination			Total # of Diagnostic Smear examined	# of suspect with following +ve smear			Total # of +ve Diagnostic Smear			Total # of +ve suspect	Smear positivity Rate %	Smear exam / suspect
	Total	Suspect	Follow up	One	Two	Three		One	Two	Three		Total Smear	+ve smear			

QA Entry Form

Date							# Functioning Diagnostic Centers													
# Diagnostic centers checked							# Diagnostic Centers with Major Error													
Laboratory	ANSV	SPR	# Slides Collected				# slides correct	Errors						Agg. %	Mj E	Mn E	FPR %	FNR %	Sen %	Spc %
			Pos	Scanty	Neg	Total		HFN	HFP	LFN	LFP	QE	Total							