

Module 10: Quality Assurance of Sputum Microscopy

Purpose To provide the participants with an understanding of various elements of Quality Assurance and its importance in sputum smear microscopy.

Pre-requisite Modules 1–9

Module Time 1 hour 15 Minutes

Learning Objectives

At the end of this module, the participants will be able to

- Describe the elements of Quality Assurance
- Explain why internal Quality Control is important to assessing laboratory performance
- Describe the three components of External Quality Assessment (EQA)
- Prepare for a supervisory visit
- Describe the process of sampling slides for blinded smear rechecking.

Module Overview

Step	Time	Activity or Method	Content	Resources Needed
1	5 min	Presentation	Module Introduction	Slides 1–3
2	20 min	Presentation	Quality Assurance of Sputum Microscopy Quality Control	Slides 4–14
3	20 min	Presentation	Quality Assurance of Sputum Microscopy EQA	Slides 15–30
4	20 min	Interactive Exercise	Case Scenario	Slides 31–32
5	10 min	Presentation	Summary	Slide 33

Material and Equipment Checklists

- PowerPoint slides or transparencies
- Overhead projector or computer with LCD projector
- Flip chart with different colour chart markers

Teaching Guide

Slide Number	Teaching Points
1	<p><u>Module 10: Quality Assurance of Sputum Microscopy</u></p> <p>DISPLAY this slide before you begin the module. Make sure participants are aware of the transition into a new module.</p>
2	<p><u>Learning Objectives</u></p> <p>STATE the objectives on the slide</p>
3	<p>Flipchart</p>  <p><u>Content Overview</u></p> <p>(Suggested presentation technique)</p> <p>WRITE the content outline before beginning this session.</p> <p>REFER to flipchart frequently to orient participants to where they are in the module.</p> <p>EXPLAIN that these are the topics that will be covered in this module.</p>
4	<p><u>Quality Assurance and DOTS</u></p> <p>READ out the 5 principles of the DOTS component of the STOP TB strategy</p> <p>EMPHASIZE that case detection by quality assured bacteriology is an important component of the strategy</p> <ul style="list-style-type: none"> • The first priority of an NTP is case detection and cure by reliable laboratory diagnosis and effective treatment
5	<p><u>QA Graphic</u></p> <p>STATE that there are 2 parts to Quality Assurance. Quality Control and External Quality Assessment.</p>

Slide Number	Teaching Points
6	<p><u>Quality Assurance</u></p> <p>STATE the message on the slide.</p> <p>EXPLAIN that Quality Control should happen as part of everyday routine work in a laboratory.</p> <p>EXPLAIN that EQA includes on-site evaluation of the laboratory to review QC and should include on-site rereading of smears. EQA also allows participant laboratories to assess their capabilities by comparing their results with those obtained in other laboratories in the network (intermediate and central laboratory) through panel testing and rechecking.</p>
7	<p><u>Key Elements of Quality Control</u></p> <p>EXPLAIN that Quality Control consists of several key elements. STATE the key elements as listed on the slide.</p>
8	<p><u>QC: Laboratory Arrangement and Administration</u></p> <p>STATE the message on the slide.</p>
9	<p><u>QC: Laboratory Equipment</u></p> <p>STATE the message on the slide.</p> <p>EMPHASIZE that it is essential to have a good quality functional microscope.</p>
10	<p><u>QC: Specimens and Request forms</u></p> <p>STATE the message on the slide</p> <p>EMPHASIZE that specimen collection process is critical for good quality AFB microscopy. The test result is only as good as the specimen received for AFB microscopy.</p>
11	<p><u>QC: Staining Reagents</u></p> <p>STATE the message on the slide.</p>
12	<p><u>QC: Staining and Smear Examination</u></p> <p>STATE the message on the slide.</p> <p>EXPLAIN that if there is a problem with the positive and negative controls, fix the problem before reporting patient smears. Some problems may require repeating all of the patient smears in a failed staining batch.</p>

Slide Number	Teaching Points
13	<p><u>QC: Recording and Reporting</u></p> <p>STATE the message on the slide</p> <p>EXPLAIN that workload statistics for the number of smears examined and the percentage of positive smears should be determined each month. Analyze these results on monthly basis to detect changes which may indicate problems with AFB microscopy</p>
14	<p><u>QC: Key Points</u></p> <p>STATE the message on the slide</p>
15	<p><u>QA Graphic</u></p> <p>STATE that EQA is the second component of Quality Assurance</p>
16	<p><u>What is External Quality Assessment (EQA)?</u></p> <p>DEFINE EQA as stated on the slide.</p>
17	<p><u>Why EQA?</u></p> <p>EMPHASIZE that EQA is seeking to identify problems and make corrective actions to improve laboratory performance.</p> <p>STATE that EQA should not be used to punish laboratories or their staff; it is designed to make them better and in doing so, improve the performance of the NTP and TB control in the country</p>
18	<p><u>EQA: Conducted at All Levels of Testing</u></p> <p>HIGHLIGHT the laboratory network structure</p> <ul style="list-style-type: none"> • National Reference Laboratory for the TB Program should play an essential role in the organization, management and maintenance of high quality testing services. • Intermediate or regional or provincial level laboratories perform more complex testing and should be able to provide supervision, monitoring, training and Quality Assurance to peripheral laboratories. • Peripheral laboratories are located at primary health centers or district hospitals and functions include performing sputum microscopy and internal QC.
19	<p><u>EQA Methods</u></p> <p>EXPLAIN that there are three methods for conducting EQA.</p>

Slide Number	Teaching Points
20	<p><u>What is On-site Evaluation?</u></p> <p>STATE the message on the slide.</p>
21	<p><u>Ensuring a Productive Site Visit</u></p> <p>STATE that a laboratory to receive an on-site evaluation needs to organize itself properly.</p> <ul style="list-style-type: none"> • Determine the date of the visit so that workflow can be adjusted (e.g. advise the TB clinic) • Share concerns or problems with equipment, staffing or supplies with the supervisor during the visit
22	<p><u>What is Panel Testing?</u></p> <p>STATE the message on the slide.</p>
23	<p><u>What Use AFB Microscopy Panel Testing?</u></p> <p>STATE the message on the slide.</p>
24	<p><u>What is Blinded Rechecking?</u></p> <p>STATE the message on the slide.</p>
25	<p><u>Why use Blinded Rechecking?</u></p> <p>EMPHASIZE that the first priority of the NTP is case detection and cure by reliable diagnosis and effective treatment</p> <p>STATE that case finding depends heavily on laboratory diagnosis, the laboratory network must function well in order to assist the NTP in treating the patients to achieve a cure and improve the wellbeing of the individual, the community and the country</p> <ul style="list-style-type: none"> • The only EQA method to provide reliable assurance that a country has an effective AFB microscopy network is blinded rechecking
26	<p><u>How is Blinded Rechecking Done?</u></p> <p>STATE the message on the slide.</p> <p>EMPHASIZE the importance of clearly and legibly labeling the slide, and storing all slides in correct order</p> <p>MENTION that results of blinded rechecking should be sent to the Laboratory supervisors</p>

Slide Number	Teaching Points
27	<p><u>Sampling from Laboratory Register</u></p> <p>EMPHASIZE the slides are the selected from the laboratory register. It is essential that all the slides randomly selected from the routine work can be easily retrieved from the stored slides using the laboratory serial number.</p>
28	<p><u>Technicians Responsibilities</u></p> <p>STATE the message on the slide</p>
29	<p><u>EQA Leads to better Laboratory Performance</u></p> <p>EMPHASIZE that EQA aims to improve AFB microscopy performed in a laboratory by identifying an resolving problems.</p>
30	<p><u>EQA Key Points</u></p> <p>STATE the message on the slide.</p>
31	<p><u>Scenario:</u></p> <p>READ the scenario</p> <p>EXPLAIN the purpose of the exercise is to provide an opportunity to apply what has been learned about quality assurance.</p>
32	<p><u>Scenario: Instructions</u></p> <p>ASK participants to consider a process of on-site evaluation. What evidence will you need to have available to support your work performance. How they might begin to respond to the doctor:</p> <p>GUIDE participants to think of elements of quality control and external quality assessment.</p> <p>RECORD participant responses on flipchart. ALLOW 15 minutes for responses before transitioning to the next slides that summarize anticipated responses.</p>

Slide Number	Teaching Points
33	<p data-bbox="557 201 829 233"><u>Analysis of Exercise</u></p> <p data-bbox="557 275 1300 464">EMPHASIZE that this exercise aims to demonstrate the importance of all aspects of quality assurance in achieving reliable and accurate AFB microscopy. After the participants have had an opportunity to respond, and you have recorded their results on the whiteboard or flipchart, DISCUSS the comments on the slide</p> <p data-bbox="557 512 1276 575"><i>NOTE: This slide is animated to highlight each key aspect contributing to a correct result one at a time.</i></p> <p data-bbox="557 606 854 638">CORRECT SPECIMEN:</p> <p data-bbox="557 638 1349 890">STATE the smear has to be made correctly from a representative portion of the sample. STATE that each specimen is labeled with a unique patient identification number and is submitted with a completed request for sputum examination form. The laboratory has procedures in place which ensure that the patient identification on the specimen matches that on the request form. This ensures that the laboratory has received the correct specimen.</p> <p data-bbox="557 890 781 921">CORRECT TEST:</p> <p data-bbox="557 921 1333 1079">STATE that the laboratory has procedures for performing sputum smear microscopy and the test used is the ZN stain. By ensuring that the procedures are readily available in the laboratory we can be assured that the correct test has been performed.</p> <p data-bbox="557 1110 883 1142">QUALIFIED TECHNICIAN</p> <p data-bbox="557 1163 1300 1320">STATE that the microscopist performing the sputum smear microscopy has received training or refresher training and is therefore qualified to perform the test. Staff academic- and training- records provide evidence that they are competent to undertake the work</p> <p data-bbox="557 1331 1243 1362">The register is signed by the person performing the test.</p> <p data-bbox="557 1394 867 1425">CORRECT EQUIPMENT</p> <p data-bbox="557 1425 1317 1551">STATE that the microscope used to perform the microscopy is kept in good working order and there are maintenance and cleaning records available. There assures that the correct equipment has been used</p>

Slide Number	Teaching Points
33 Continued	<p><u>Analysis of Exercise Continued</u></p> <p>CORRECT REAGENTS STATE that the quality control records of stains demonstrate that the reagents are working as expected. STATE that having a correct, up-to-date SOP which is readily available in the laboratory is an important part of demonstrating competency</p> <p>EXTERNAL QUALITY ASSESSMENT STATE that when EQA is in place a sample of the laboratory's routine work is checked at another laboratory. This provides confidence in the overall performance of the laboratory.</p> <p>STATE that when all of the above components of quality assurance are in place the microscopist can have great confidence that the results they report are the CORRECT RESULTS</p>
34	<p><u>Summary</u></p> <p>READ the message on the slide</p> <p>ANSWER any questions or queries</p>
	<p><u>NOTE</u></p> <p>At this time Final Examination can be conducted</p> <p>EXPLAIN participants will go to laboratory for final examination on reading the stained panel smears</p> <p>Refer to Section 5, for Final examination details.</p>