Module 10:

Quality Assurance of AFB Microscopy

Learning Objectives

At the end of this module, you 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
- Prepare for a supervisory visit
- Describe the process of sampling slides for blinded smear rechecking

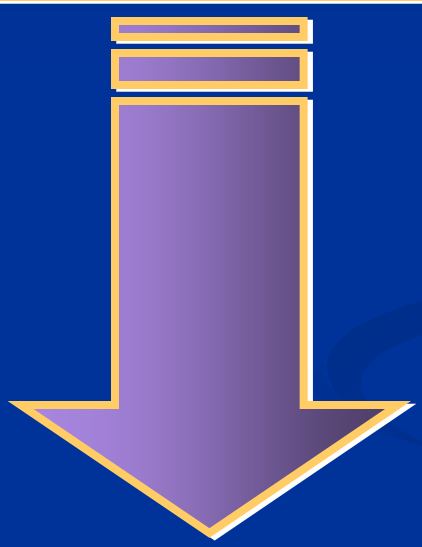
Content Overview

- What is Quality assurance?
- Quality Control in the TB laboratory
- EQA and why is it important
- EQA Methods
  - Panel Testing
  - On-Site Evaluation
  - Blinded Rechecking

Quality Assurance and DOTS

- Sustained political commitment to TB control
- Case detection by quality assured bacteriology.
- Directly observed treatment (DOT)
- Uninterrupted supply of drugs
- Standardised recording and reporting system

Quality Assurance



Quality Control

External Quality Assessment

Quality Assurance

- QC should be carried as part of everyday routine work
  - Includes instrument checks and checking new lots of staining solutions
- EQA is a process to assess laboratory performance.
  - Allows participating laboratories to assess their capabilities by comparing their results with those in other laboratories in the network

Key Elements of Quality Control

- Administration
- Laboratory Equipment
- Specimens and Request Form
- Staining Reagents
- Staining and Smear Examination
- Reporting

Quality Control:

Laboratory Arrangement and Administration

- Perform Sputum microscopy in a secure, dedicated work space
- Provide appropriate staff training and monitor their performance
- Methods must comply with NTP guidelines

Quality Control: Laboratory Equipment

- Maintain all laboratory equipment in a good working condition
- Keep dated service records for all equipment
- Monitor microscopes and balances regularly to ensure consistent performance

QC-Specimens and Request forms

- Ensure request forms are completed and specimens correctly labeled.
- Reject specimens that are incorrectly labeled, leaking, or in broken containers.
- Record the date specimens arrive in the laboratory.
- Evaluate the quality of sputum specimens.
- Record and monitor the number of salivary specimens received by the laboratory.

Quality Control: Staining Reagents

- Label all reagents with the name, date of preparation, and the date first opened.
- Indicate date received, if staining reagents are prepared in another laboratory
- Any material found to be unsatisfactory should be recorded as such and removed from the laboratory immediately so it is not used.
- Limit stocks to six months' supply. Rotate stock to ensure that oldest material is used first.

Quality Control: Staining and Smear Examination

- Filter carbol fuchsin regularly.
- Include positive and negative controls at least weekly.
- Read control slides before patient smears.
- Record the results of control smears

Quality Control: Recording and Reporting

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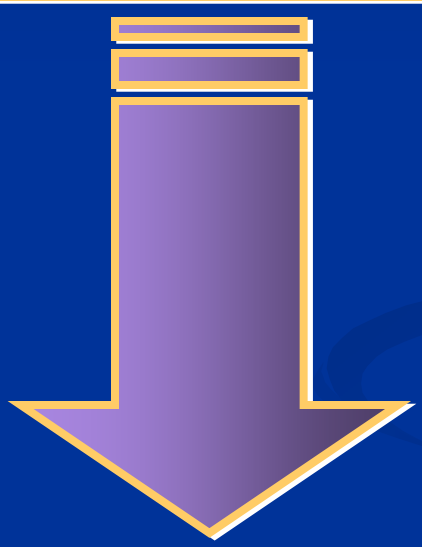
- Report microscopy results within 24 hours after the sputum specimen is received.
- Record all work performed in standard format into the Laboratory Register
- Analyze microscopy results on monthly basis to detect changes which may indicate problems.

Quality Control: Key Points

- QC activities should be part of everyday laboratory workload
- It is the responsibility of every technician
- Demonstrates that the results generated by a laboratory are likely to be reliable and accurate
- Results of QC activities must be documented

Quality Assurance



Quality Control

External Quality Assessment

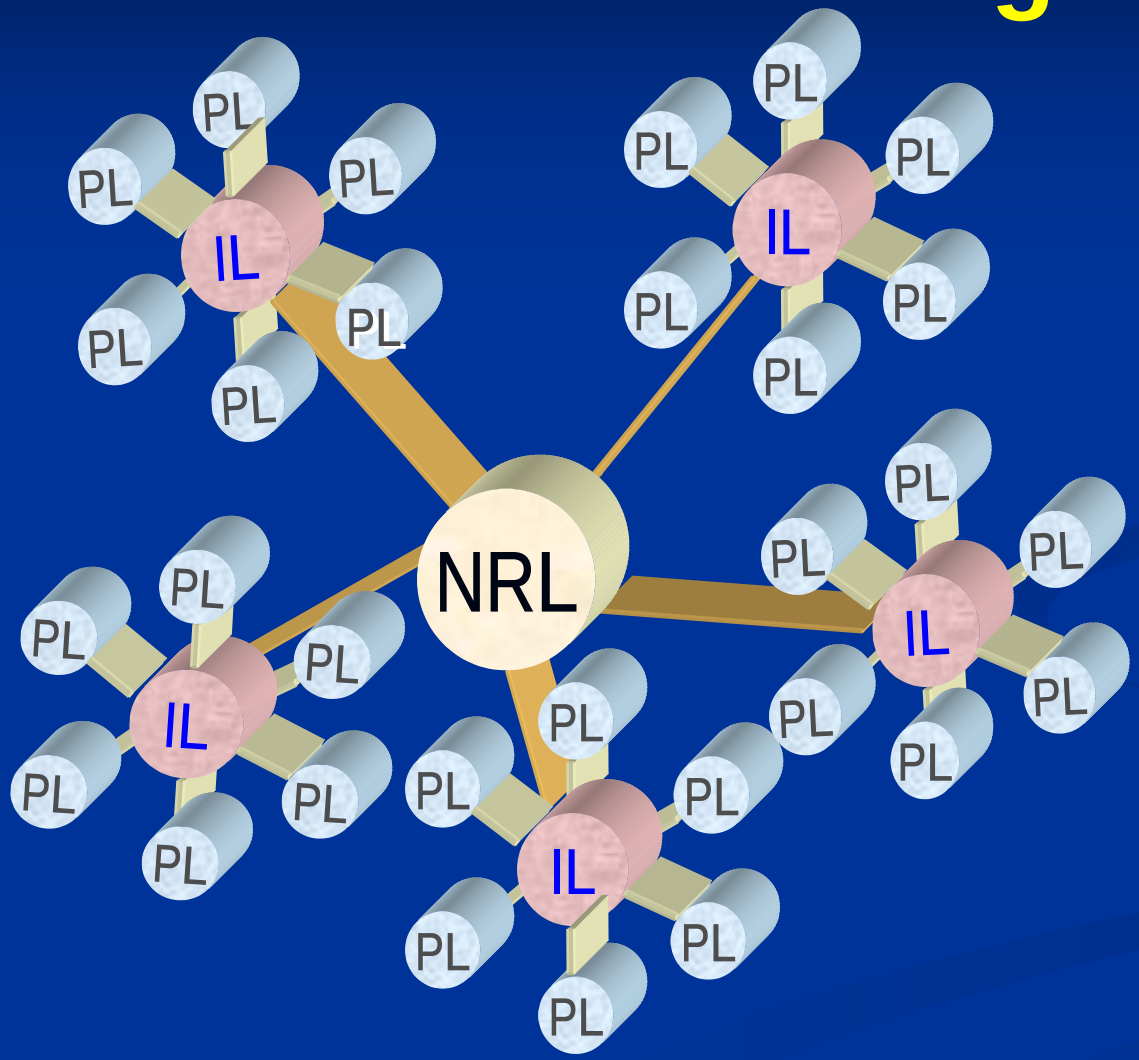
What is External Quality Assessment (EQA)?

A process to assess laboratory performance. EQA allows participating laboratories to assess their capabilities by comparing their results with those in other laboratories in the network.

Why EQA?

- Identifies errors and is used to improve performance across the laboratory network
- An important tool for communicating with and motivating staff
- Designed to resolve problems and not to punish staff

EQA: Conducted at <u>All</u> Levels of Testing

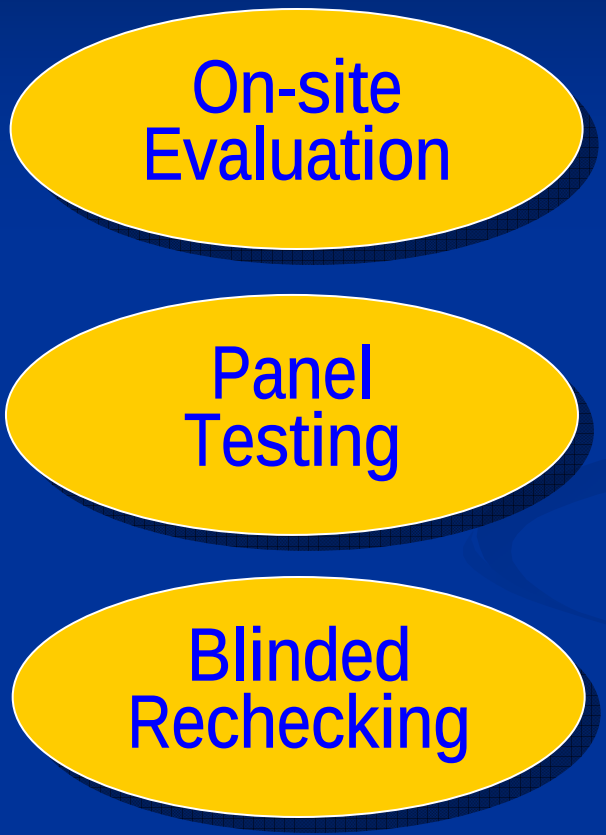


NRL: National Lab

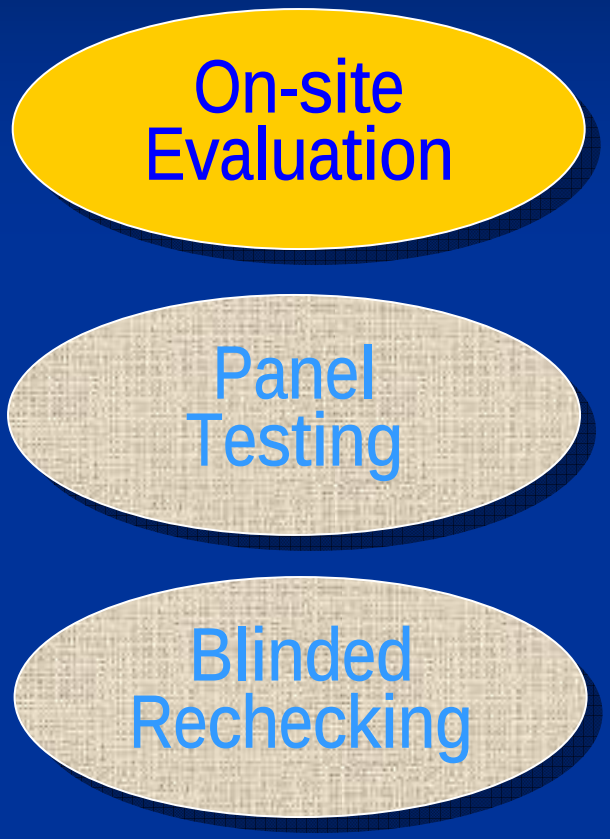
IL: Intermediate Lab

PL: Peripheral lab

EQA Methods



What is On-site Evaluation?



Periodic site visits to assess laboratory practices

- Learn “where we are?”
- Identifies what is ‘good’ and what areas need improving
- Collect information for
  - Planning & implementation
  - Monitoring
  - Continuous improvement

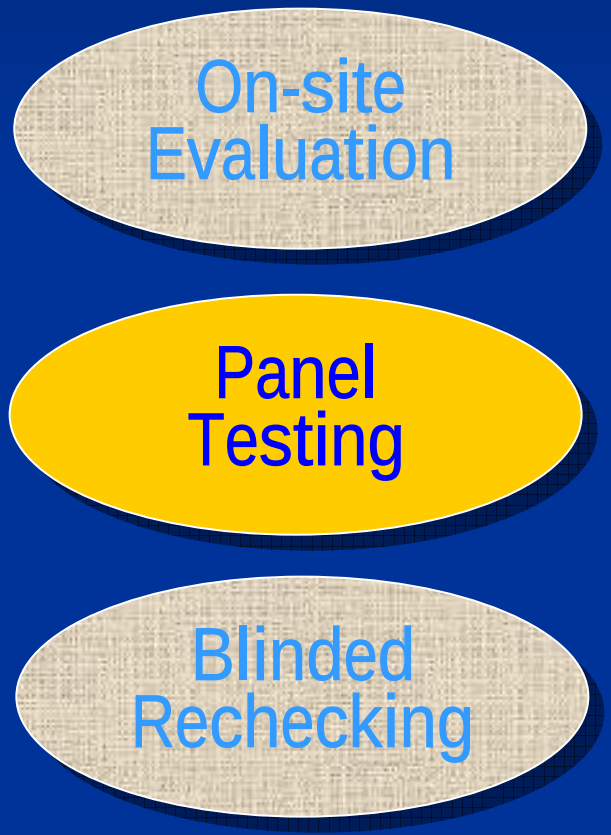
Ensuring a Productive Site Visit

- Supervisory visits will take time
- All components of AFB microscopy will be evaluated
- Adjust work flow

These visits are opportunities to

- learn
- discuss concerns
- solve problems

What is Panel Testing?

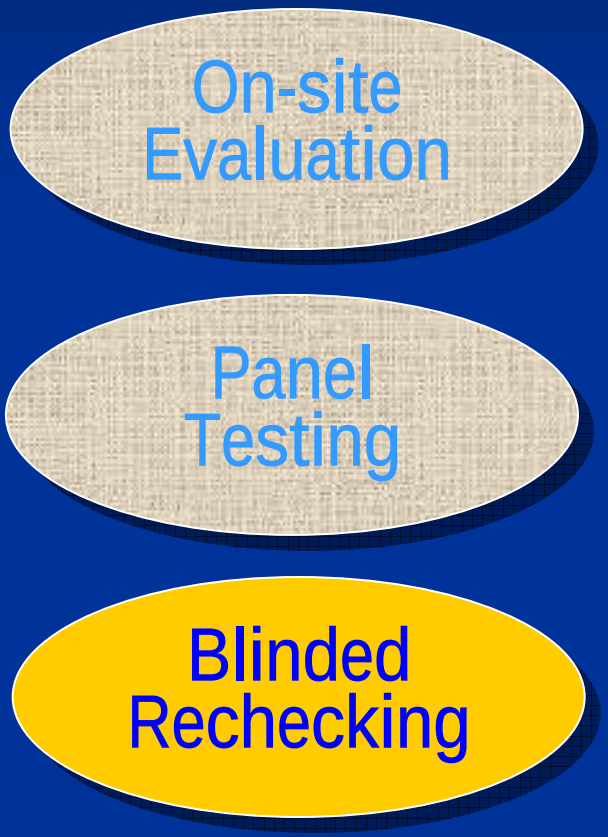


- A number of slides are sent to the laboratory.
- Microscopy center performs AFB smear microscopy and report results.
- Results indicate quality of personnel performance and test site operations.
- Results are often compared across several testing sites.

Benefits of Panel Testing

- Monitors performance in the absence of rechecking programs
- Identifies laboratories with serious deficiencies
- Evaluates proficiency of technicians following training
- Supplements rechecking programs

What is Blinded Rechecking?



- Based on Lot Quality Assurance Sampling (LQAS); a random selection of specimens are collected from the routine workload at the test site and sent to the reference laboratory for validation
- Used to confirm that a laboratory meets national performance goals
- Detects errors

Why use Blinded Rechecking?

- The only EQA method to provide reliable assurance that a country has an effective AFB microscopy network
- Reflects reality of routine performance by checking:
  - specimen quality
  - smear technique
  - stain performance
  - accuracy of reading
- Provides motivation to staff

How is Blinded Rechecking Done?

1. Test lab stores all smears
2. Random sample collected
3. Sampled slides sent to control lab
4. Slides rechecked in blind reading
5. Results analysed
6. Report prepared for test lab
7. Follow-up site visit (if indicated)

Lab Serial Number	Date	Name	Sex M/F	Name of treatment Unit	Address New Patients	Reason for examination		Results of specimen			Signature	Remark
						Diagnosis	Follow Up	1	2	3		
1								Neg	Neg	Neg		
2								Neg	Neg	Neg		
3								Neg	Neg	neg		
4								Neg	5/100	Neg		
5								Neg	Neg	Neg		
6								1+	2+	7 afb		
7								2+	6 afb	Neg		
8								Neg	Neg	Neg		
9								Neg	Neg	Neg		
10								Neg	Neg			
11								Neg	Neg	Neg		
12								Neg				
13								Neg	Neg	Neg		
14								1+	Neg	Neg		
15								Neg	Neg	Neg		
16								Neg				
17								Neg	Neg	Neg		
18								Neg	Neg	Neg		
19								3+	1+			
20								Neg	Neg	Neg		
21								8 afb	Neg	4 afb		

Technicians' Responsibilities

- Be a willing participant in the EQA program
- Ensure all slides are stored in correct order
- Maintain EQA records within the laboratory
- Communicate outcomes to supervisors
- Implement recommended corrective actions promptly

EQA Should Lead to Better Laboratory Performance

EQA Key Points

- EQA may use a combination of methods
  - On-site evaluation
  - Panel Testing
  - Blinded rechecking
- Each method has distinct advantages and disadvantages and resource requirements
- A country-wide, functional program for blinded rechecking should be a long term goal of the NTP

Scenario

Your country has a GREAT Football team!!!

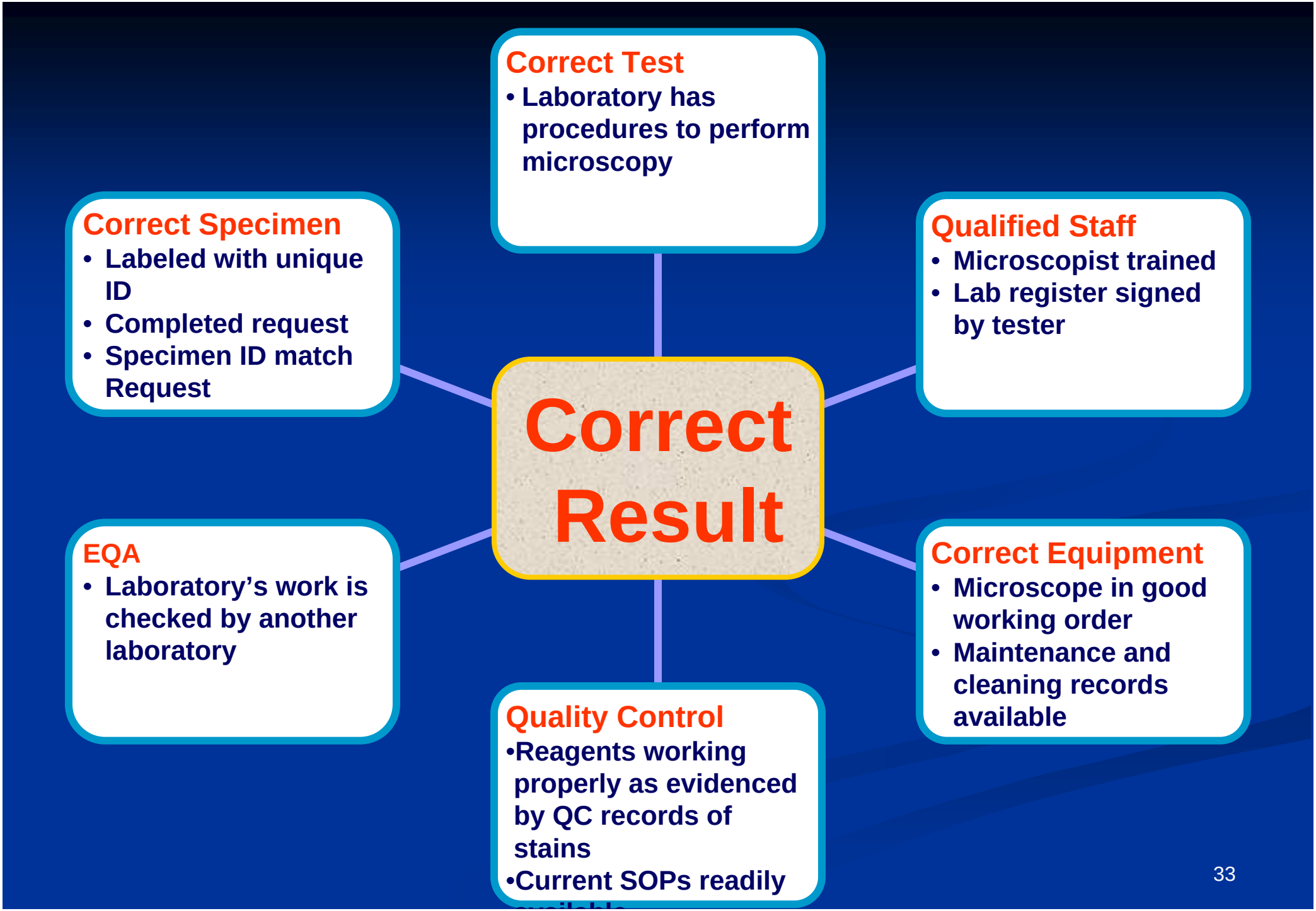
A FAMOUS player has agreed to train with your National Football team. However, upon arrival, the player admits that he has had a cough for one month. Sputum samples are sent to your lab and you send out results of 2+ AFB on three consecutive specimens.

His doctor does not believe your results!

How can you show your results are correct?

Scenario: Instructions

- Consider process of on-site evaluation
- What evidence will you have to support your work performance?
- Record responses on flip chart (15 minutes)


Correct Test
• Laboratory has procedures to perform microscopy
Correct Specimen
• Labeled with unique ID
• Completed request
• Specimen ID match Request
Qualified Staff
• Microscopist trained
• Lab register signed by tester
Correct Result
EQA
• Laboratory's work is checked by another laboratory
Correct Equipment
• Microscope in good working order
• Maintenance and cleaning records available
Quality Control
•Reagents working properly as evidenced by QC records of stains
•Current SOPs readily

Summary

- What are the elements of quality assurance?
- What is Quality Control?
- What is blinded slide rechecking?
- For blinded smear rechecking, how does the technician store the slides?
- What should you do to make sure that the Ziehl-Neelsen reagents are working properly?