



Laboratory Quality Management System

Module 15: External Quality Assessment

Venue:

Presenter:

Date:

1. Introduction

The most commonly employed assessment method is EQA



Learning Objectives

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

- Discuss the importance of an EQA program in improving the quality of laboratory test results.
- Describe at least three EQA methods and the advantages and disadvantages of each.
- Outline a method to investigate an unacceptable test result from an EQA sample.



Module Outline

- Introduction

- Proficiency Testing (PT)

- Other External EQA methods



Scenario

A newly appointed laboratory supervisor has begun reviewing past EQA results, and observes poor Gram stain performance.



“How should the laboratory investigate this problem?”



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The Quality Management System



External Quality Assessment

**A system for objectively checking the
laboratory's performance using an
external agency or facility**



EQA Methods/Types

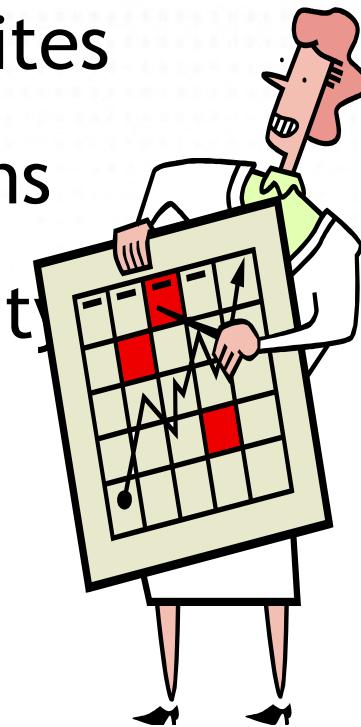
Proficiency
Testing

Rechecking
Retesting

On-site
Evaluation

Benefits: External Quality Assessment (EQA)

- comparison among different test sites
- early warning for systemic problems
- objective evidence of testing quality
- areas that need improvement
- training needs



EQA Benefits

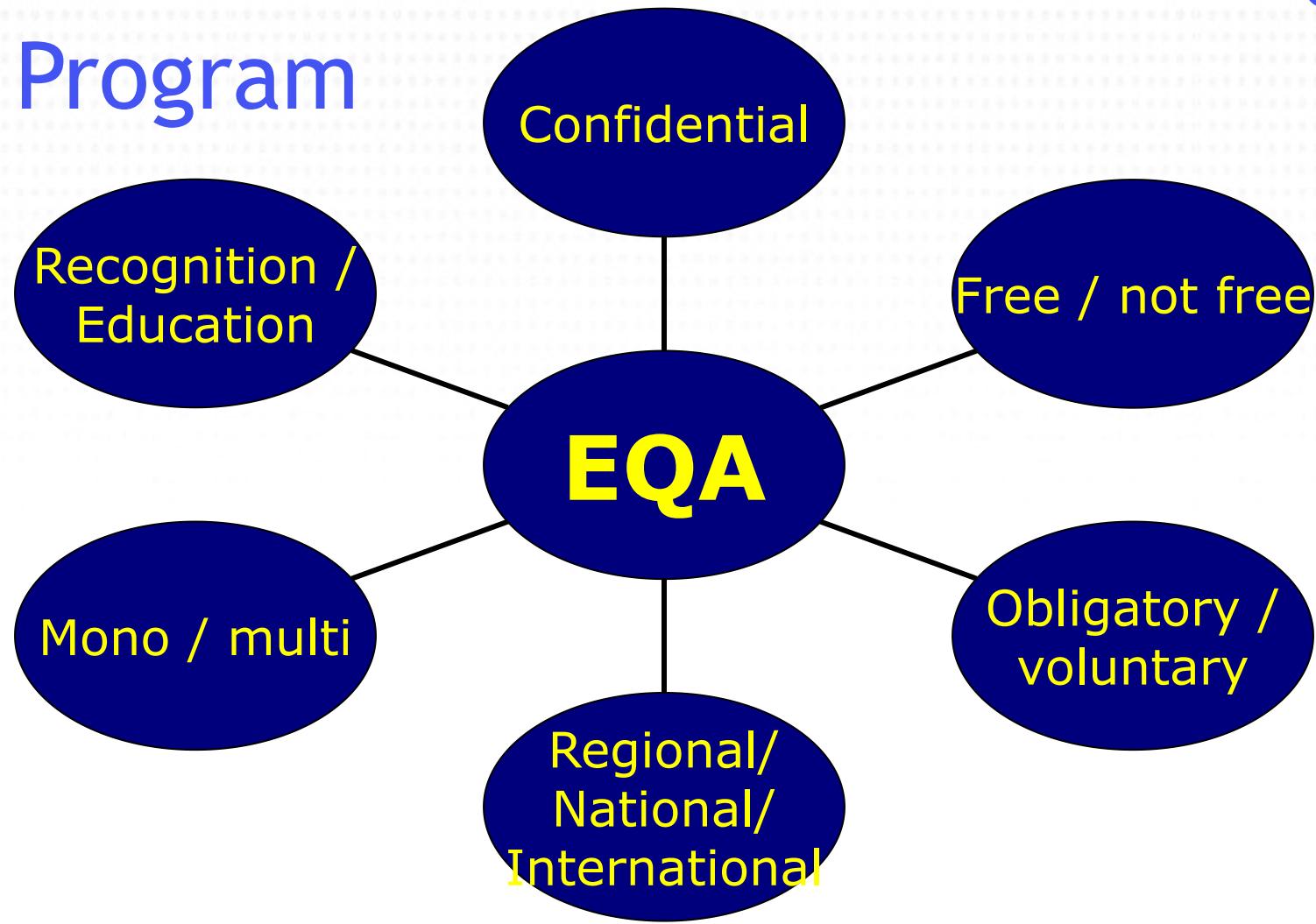
Laboratory
oriented
objectives



Public Health
oriented objectives



Characteristics of an EQA Program



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EQA

- important for improvement
- a measure of laboratory performance



2. Proficiency Testing

Definition

ISO/IEC Guide 43-1:1997

“Proficiency testing schemes (PTS) are interlaboratory comparisons that are organized regularly to assess the performance of analytical laboratories and the competence of the analytical personnel.”



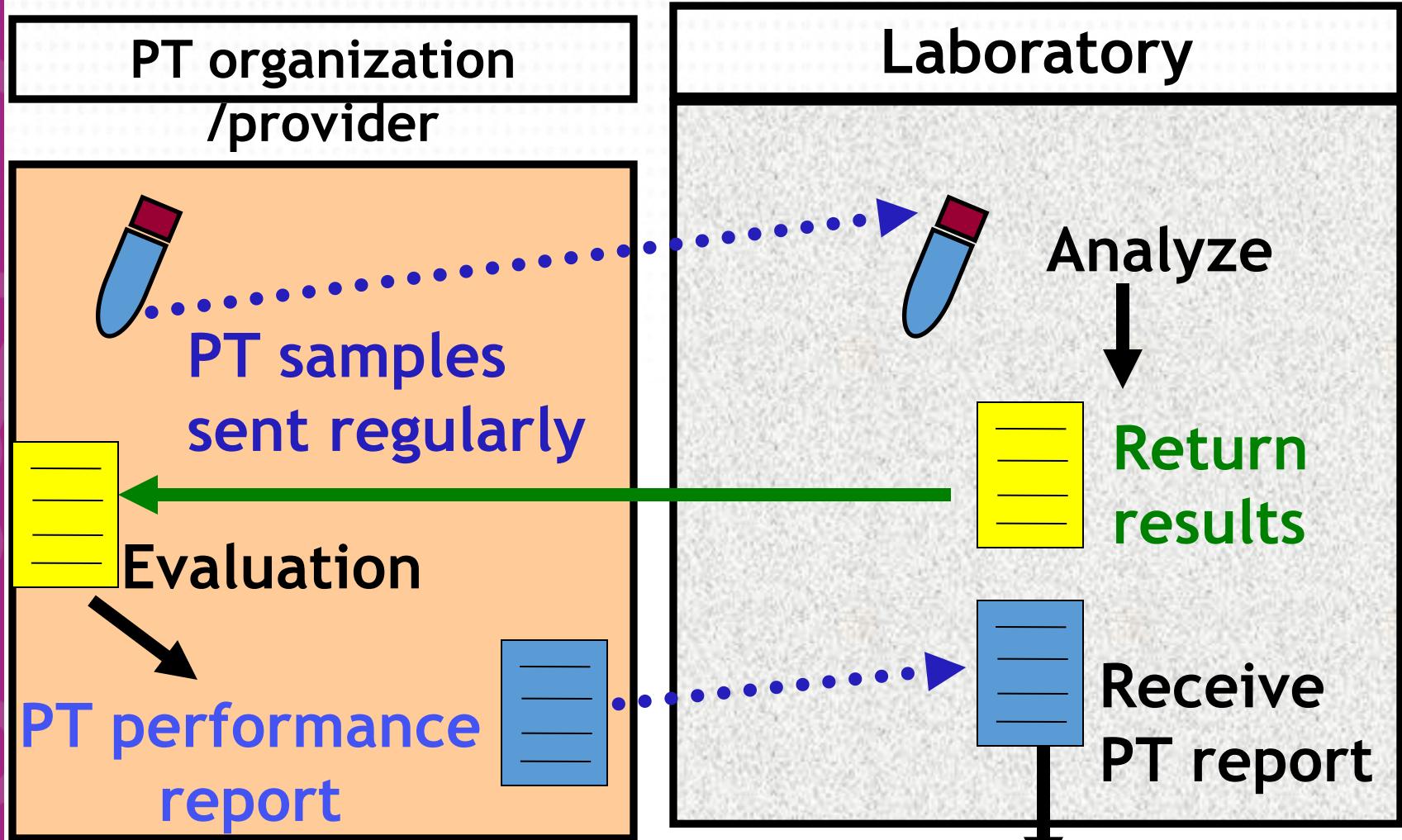
Definition Proficiency Testing

CLSI GP27-A2 27:8

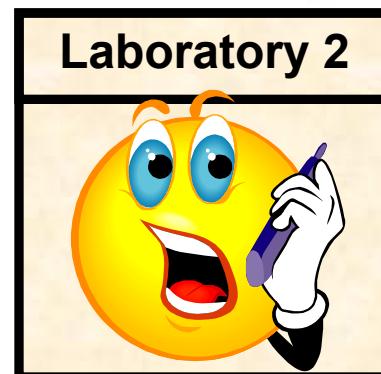
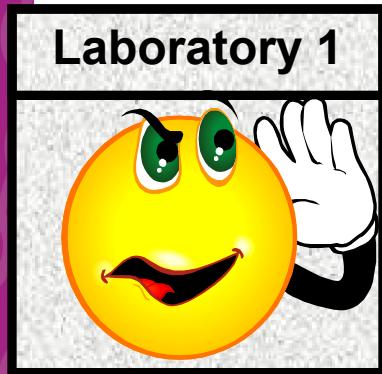
“A program in which multiple samples are periodically sent to members of a group of laboratories for analysis and/or identification; whereby each laboratory’s results are compared with those of other laboratories in the group and/or with an assigned value, and reported to the participating laboratories and others.”



PT Process

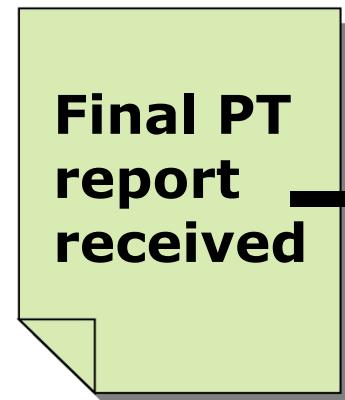


PT: Roles of Laboratory



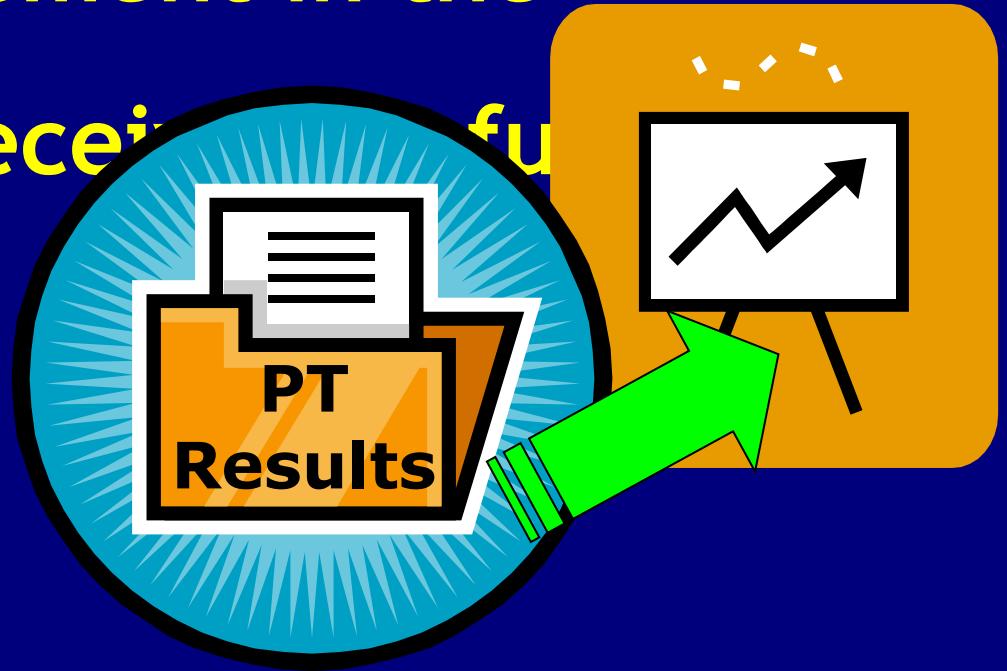
No discussion
between labs

PT sample **Patient sample**
Analyze same manner
with same personnel



Improvement

Information received from PT participation must be directed toward improvement in the laboratory to receive full credit.

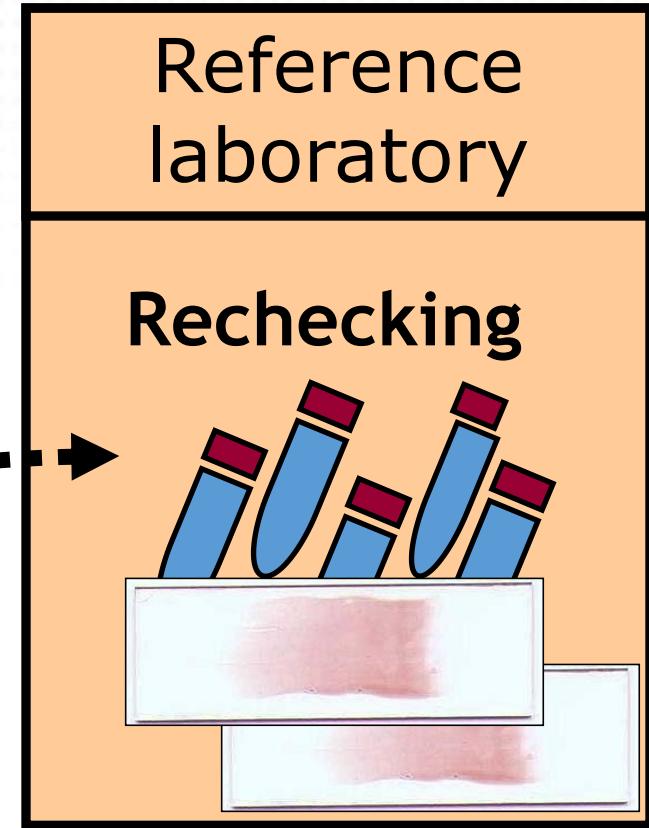
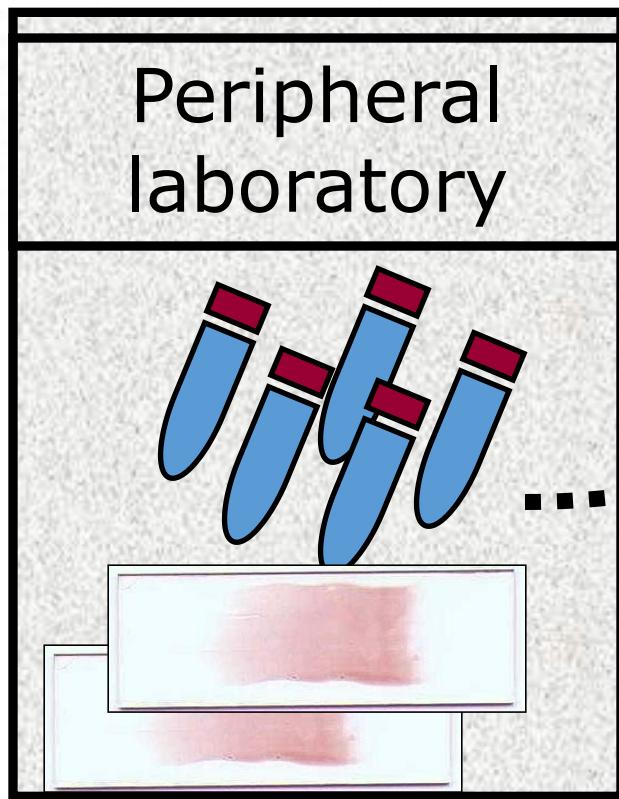


PT Limitations

- PT results are affected by variables not related to patient samples
- PT will not detect all problems in the laboratory
- PT may not detect problems with pre- and postexamination procedures

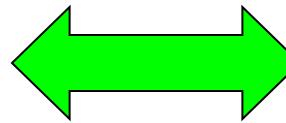


3. Other EQA Methods Rechecking/Retesting



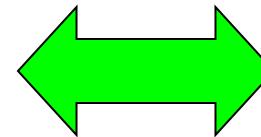
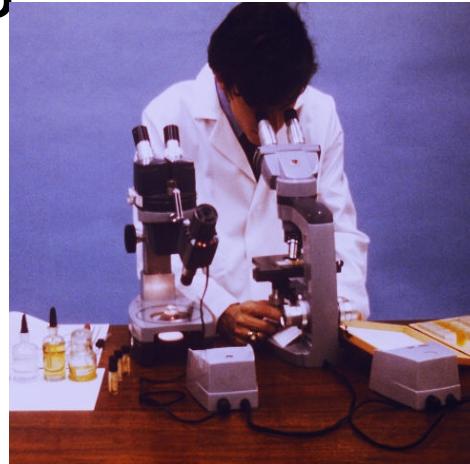
Retesting

- tested by reference laboratory
- performed on dried blood spots or serum
- not blinded
- statistically significant
- primarily used to assess HIV rapid testing



Rechecking

- samples must be collected randomly
- avoid systematic sampling bias
- statistically significant
- resolve discrepancies
- effective feedback
- primarily AFB



Comparison of rechecking non-blinded and random blinded smears for acid-fast bacilli

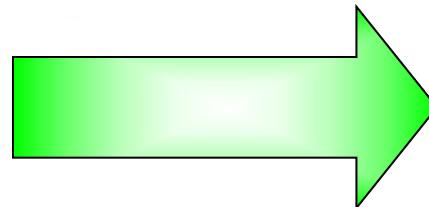
Performance characteristics measured	Non-blinded sample (1998)	Random blinded sample (2002)
State A-sensitivity	99.7%	86.7%
State B-sensitivity	98.9%	84.7%
State A-specificity	99.8%	99.1%
State B-specificity	99.9%	99.7%



Martinez A, et al. Int J Tuberc Lung Dis 2005;9(3):301-5. Supranational Reference Laboratory

On-site Evaluation

- to obtain a realistic picture of laboratory practices
- to provide assistance with problem areas



Periodic visits



Laboratory



External group or Organizer

AFB Microscopy Comparison of performance before and after on-site monitoring

	BEFORE (%)	AFTER (%)
No sand bucket	96	27
No decontamination of sputum cups	60	23
No disinfectant	31	4
No biohazard waste bin (covered)	48	8
No lab coats	48	46
Technologists do not wash hands	17	4
Shortage of lab reagents	75	27
Improper sputum collection	60	31
Improper filling of laboratory register	29	4
Improper labeling	31	13

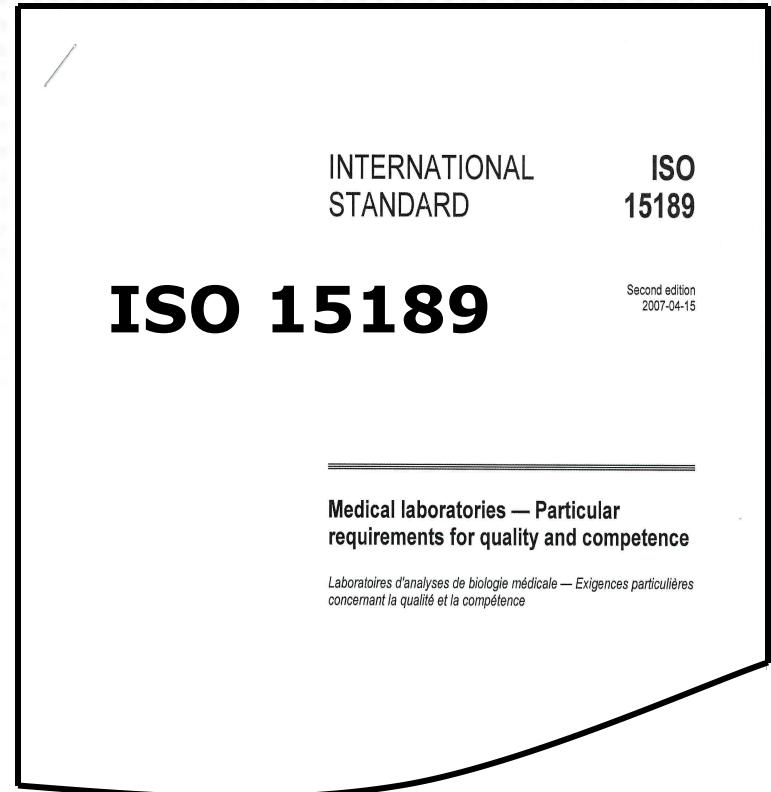
4. Comparison of PT and Rechecking methods

Characteristics	PT	RC
Interlaboratory comparison	Yes	Yes
Simulated samples	Yes	No
Real samples	Yes/No	Yes
Time and resources needed	Less	More
Analytes evaluated	Many	Few



EQA Participation

- Recommended for all laboratories
- Required by ISO

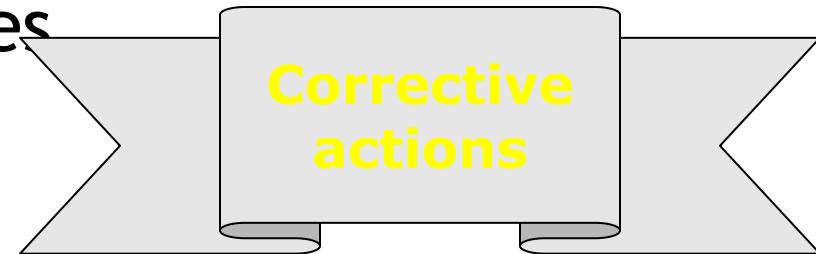


Managing EQA in the laboratory

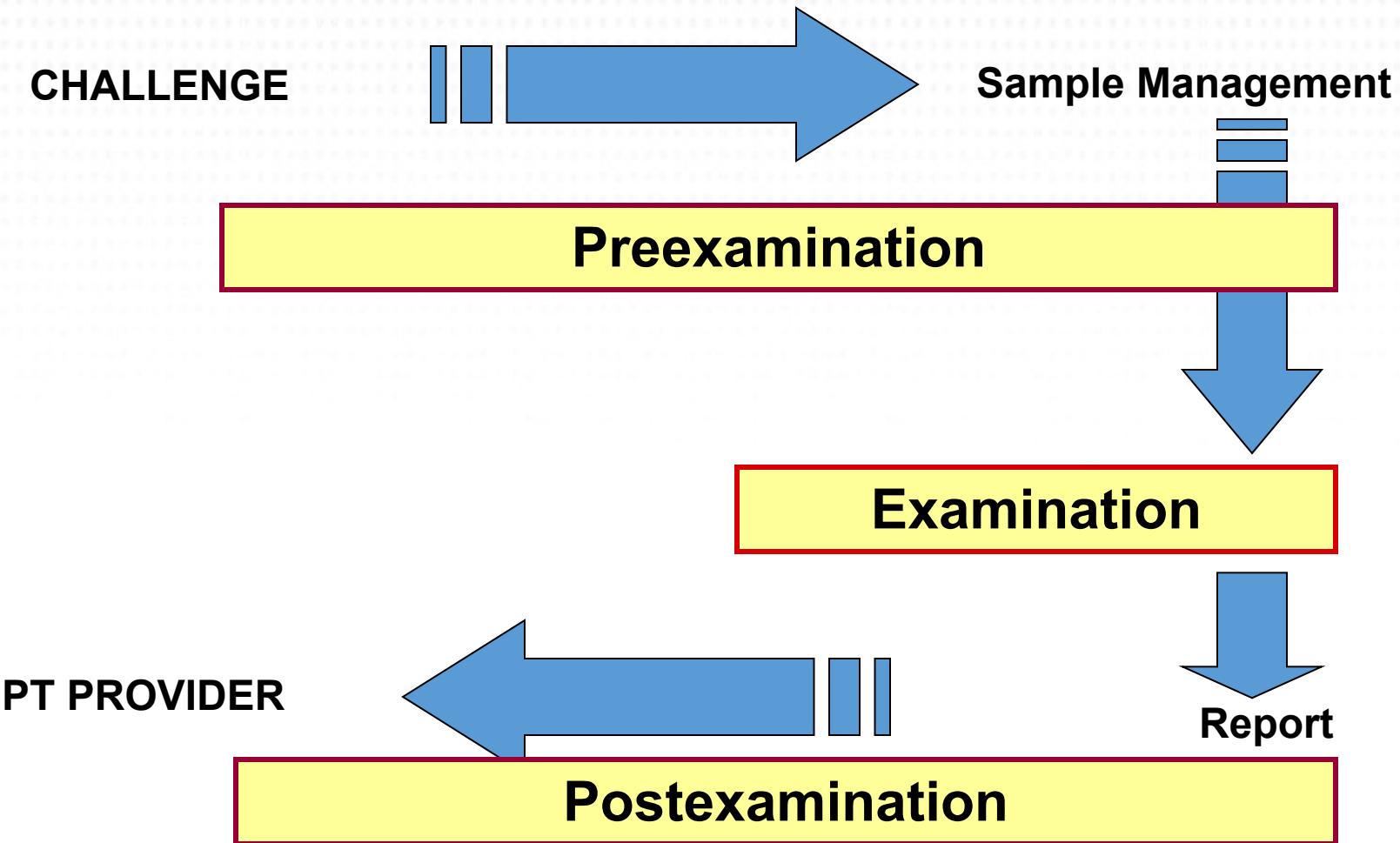
Management Process

- handle and analyze EQA samples
- treat EQA samples same as patient
- monitor and maintain records
- investigate deficiencies
- manage corrective action efforts
- communicate outcomes

EQA results



EQA performance problems



EQA Should Lead to Actions



Assessment

1. Discuss the importance of an EQA program in improving the quality of laboratory test results.
2. Describe at least three EQA methods and the advantages and disadvantages of each.
3. Outline a method to investigate an unacceptable test result from an EQA sample.



Summary

- EQA is a system for objectively checking the laboratory's performance using an external agency or facility
- All laboratories should participate in EQA
- Several methods of EQA in use
- EQA samples must be treated the same as patient samples



Key Messages

- EQA uses valuable resources, make best possible use
- EQA should not be punitive
- EQA should be viewed as educational
- EQA can help direct improvement efforts
- EQA is a critical element of a quality management system



References

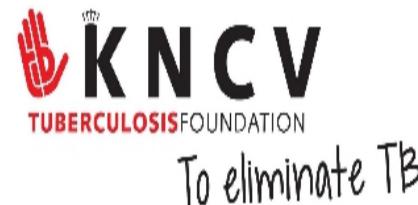
ISO 15189:2012 Medical Laboratories -
Requirements for Quality and Competence

« Clause 4.14»

- CLSI
- ASLM



Acknowledgement



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