Annex 10-A: Laboratories in Mexico that Support the National Tuberculosis (TB) Control Program: Unblinded / Blinded

Introduction Laboratories in Mexico that support the national tuberculosis (TB) control program were involved in an acid-fast bacilli (AFB) microscopy external quality assurance pilot program, which includeed rechecking 100% of smears identified as AFB-positive and 10% of smears identified as AFB-negative by the local laboratories. Very few errors were detected in Mexico using non-random selection and unblinded rechecking of the slides.

This study aimed at evaluating the results from this 1-year pilot program involving blinded rechecking of randomly selected AFB slides from local TB laboratories in two Mexican states and at determining its feasibility for future implementation.

Design To reduce potential bias, laboratory staff from the National TB Laboratory, Institute for Epidemiological Diagnosis and Reference (InDRE), performed quarterly statistical sampling of AFB smears and on-site evaluations in local laboratories in each state. AFB smears were rechecked at the respective state laboratories with discordant results resolved at InDRE.

The results are represented in Table 1.

Table 1. Comparison of rechecking unblinded and random blinded smears for acid-fast bacilli

Performance characteristics measured in rechecking program	Unblinded 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%

A significantly greater percentage of errors were detected on the randomly selected, blinded AFB smears than on the non-randomly selected, unblinded smears.

Conclusion Random blinded rechecking provides more accurate estimates of AFB microscopy results, resulting in improved diagnosis and monitoring of treatment response.

Reference Martinez A., et al. Evaluation of new external quality assessment guidelines involving random blinded rechecking of acid-fast bacilli smears in a pilot project setting in Mexico. *International Journal of Tuberculosis and Lung Diseases* 2005;9(3):301-5.

Annex 10-B: Retesting EQA Process for HIV Rapid Test

The retesting EQA process is used for HIV rapid test monitoring.[1]

Serum or dried blood spots are collected from the client at the time of HIV rapid testing.

The serum or the dried blood spots are tested using enzyme immunoassay (EIA) at a reference laboratory, and the results of this "retest" are compared with those obtained from the final HIV rapid test result.

Usually 5-10% of HIV rapid test samples are randomly selected for retesting. A guide for determining the number to test can be found in the WHO-CDC guide on quality assurance for HIV rapid testing.[2]

The number of samples to be retested depends on the volume of testing in the laboratory.

[1] CDC/WHO HIV Rapid Test Training Package.
Available at URL: http://wwwn.cdc.gov/dls/ila/hivtraining/

[2] Guidelines for assuring the accuracy and reliability of HIV rapid testing: Applying a Quality System Approach. 2005. WHO/CDC. See Tables 2a and 2b, page 49.
Available at URLs: http://www.phppo.cdc.gov/dls/ila/default.aspx and http://www.who.int/hiv/topics/vct/toolkit/components/supply/en/index8.html

Annex 10-C: Tuberculosis (TB) Diagnostic Units in Uganda

Introduction and Objectives The settings of this study are the TB diagnostic units in Uganda.

The objectives are to assess and improve the supervision and performance of sputum smear microscopy in the peripheral diagnostic units in Uganda using a standardized laboratory checklist as a part of the on-site monitoring scheme.

Study Design A standardized checklist was developed and used during the quarterly on-site monitoring visits of the District TB and Leprosy Supervisors for five quarters from the fourth quarter of 1997 until the last quarter of 1998. Individual peripheral laboratory performance was monitored during the study period.

Results In six of the 45 Ugandan districts 48 of 304 TB diagnostic units were monitored using the checklist. A total of 208 checklists were analyzed. The situational analysis of the peripheral diagnostic units at the beginning and at the end of the study showed a marked improvement in laboratory performance in all aspects related to sputum smear microscopy (Table 1). Individual laboratory performance was monitored over five quarters, and timely response to shortcomings was provided.

Table 1. Comparison of laboratory performance before and after checklist monitoring

Checklist	**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 laboratory coats	48	46
Technicians do not wash hands	17	4
Shortage of laboratory reagents	75	27
Improper sputum collection	60	31
Improper filling of laboratory register	29	4
Improper labeling slides/containers	31	13

Conclusion The systematic use of a standardized laboratory checklist as a part of an on-site monitoring scheme can be considered an important step in improving the performance of the peripheral laboratories in Uganda through on-the-spot correction of any identified shortcomings.

Reference Aziz M, Bretzel G. Use of a standardized checklist to assess peripheral sputum smear microscopy laboratories for tuberculosis diagnosis in Uganda. *International Journal of Tuberculosis and Lung Diseases* 2002;6(4):340-9.