

# External Quality Assessment in Developing Countries: Role of WHO

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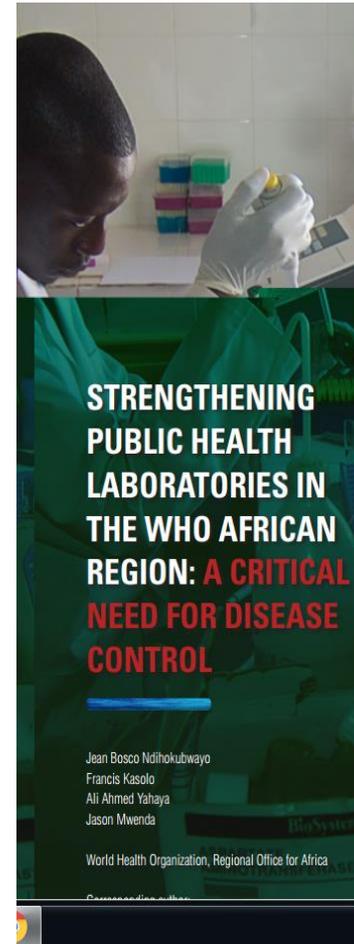
# WHA Resolution 27.62, 1974

- Advocated **strengthening of laboratory services** through the application of appropriate and cost-effective diagnostic and therapeutic procedures that are essential for the provision of quality health care and mitigation of human mortality, morbidity and misery.
- The need for an **effective, responsive, high quality medical laboratory network** within a developed and well organized health system is a recognized integral and vital part of patient services, and key to the success of the WHO disease prevention and control programs



# Resolution AFR/RC58/R2 (2008)

- Called for **strengthening of public health laboratories** in the African Region
- Urged member states to **strengthen laboratory management information systems** that will allow for the collection of regular and accurate data for use in monitoring, evaluating and planning of quality laboratory services



Despite the progress and efforts being made to strengthen laboratory capacities in the Region, challenges remain. The purpose of this document is to raise awareness on the need to strengthen public health laboratory services and propose actions for building national laboratory capacity.

En dépit des progrès et des efforts réalisés pour renforcer les capacités de laboratoire dans la région, des défis restent à relever. L'objet du présent document est de sensibiliser à la nécessité de renforcer les services de laboratoire de santé publique et de proposer des actions pour développer les capacités des laboratoires nationaux.

Apesar dos progressos e esforços verificados no reforço das capacidades laboratoriais na Região ainda existem desafios. O objetivo deste documento é aumentar a consciência da necessidade de reforçar os serviços dos laboratórios públicos de saúde e propor medidas para a capacitação dos laboratórios nacionais.

Laboratories continue to play a critical role in all disease control and prevention programmes by providing timely and accurate information for use in patient management and disease surveillance. For purposes of case management and disease control and prevention, laboratories can be grouped into two broad categories: clinical laboratories and public health laboratories.<sup>1</sup>

Public health laboratories are responsible for providing timely and reliable results primarily for the purpose of disease control and prevention. However, clinical laboratories are responsible for providing accurate diagnosis of ongoing, recent or past infections for appropriate case management. The focus of the clinical laboratory is individual patient care. However, data generated from both types of laboratories are essential for disease surveillance, control and prevention activities.

In the African Region, the situation of laboratory services is characterized by inadequate staffing, equipment and supplies. These are the main obstacles

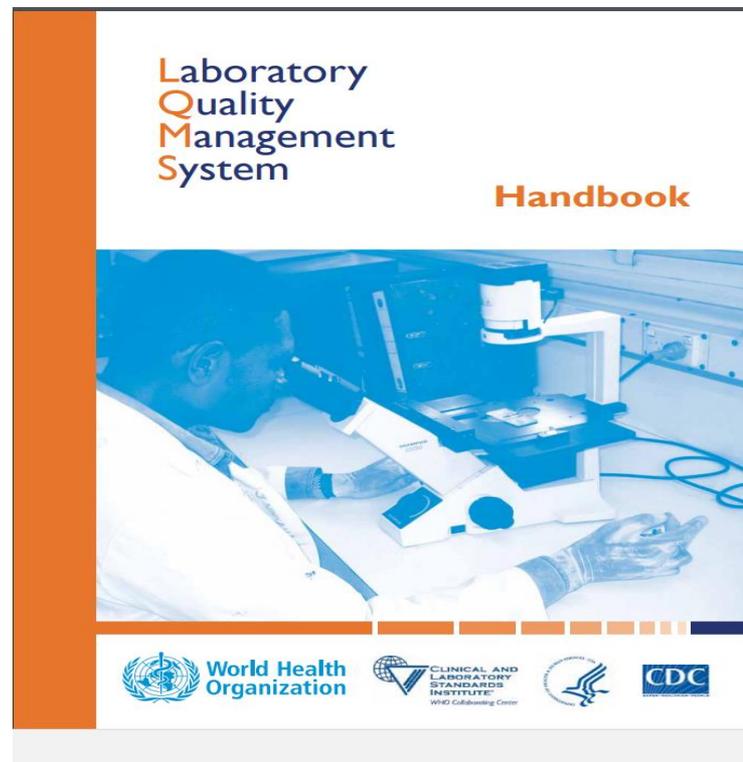
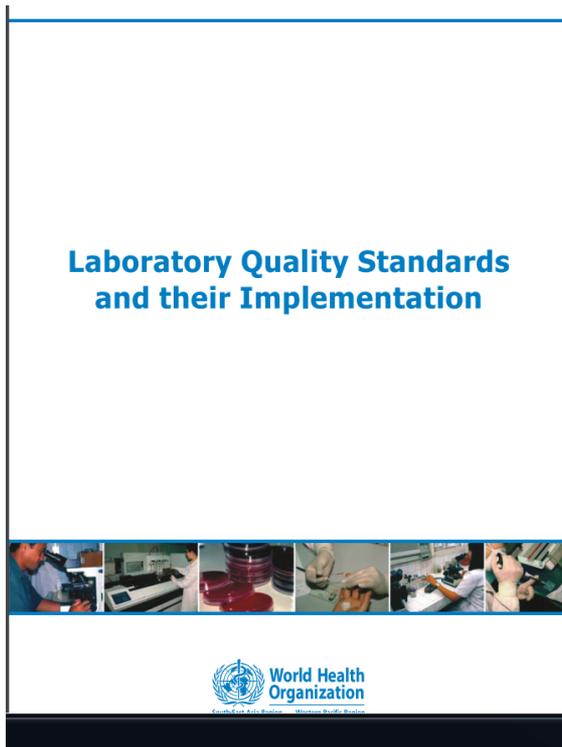
# WHO role in EQA

- Holistic approach rather than focusing on EQA alone
- Implemented in all levels of the organization
  - Headquarters Depts.
    - (Essential Medicine and Health products, HIV/AIDS, Tb and Neglected Diseases and Hepatitis Programs, Blood safety, Tuberculosis)
  - Lyons office (International Health Regulation)
  - Regional offices (AFRO, SEARO, EURO)
- Advocacy
- Technical support to member states



# Advocacy

- Publication of guidance documents on EQA



# Advocacy

Regional Publication, SEARO, No. 24

UNAIDS/96.5  
English only

## Health Laboratory Services in Support of Primary Health Care in Developing Countries

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### GUIDELINES FOR ORGANIZING NATIONAL EXTERNAL QUALITY ASSESSMENT SCHEMES FOR HIV SEROLOGICAL TESTING

January 1996

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WHO/HRP/IQC/1995  
Distr: GENERAL

UNDP/UNFPA/WHO/World Bank  
Special Programme of Research, Development and  
Research Training in Human Reproduction

## Principles of External Quality Assessment A Laboratory Manual

S.Z. Cekan, S.B. Sufi, and E.W. Wilson



World Health Organization  
1995

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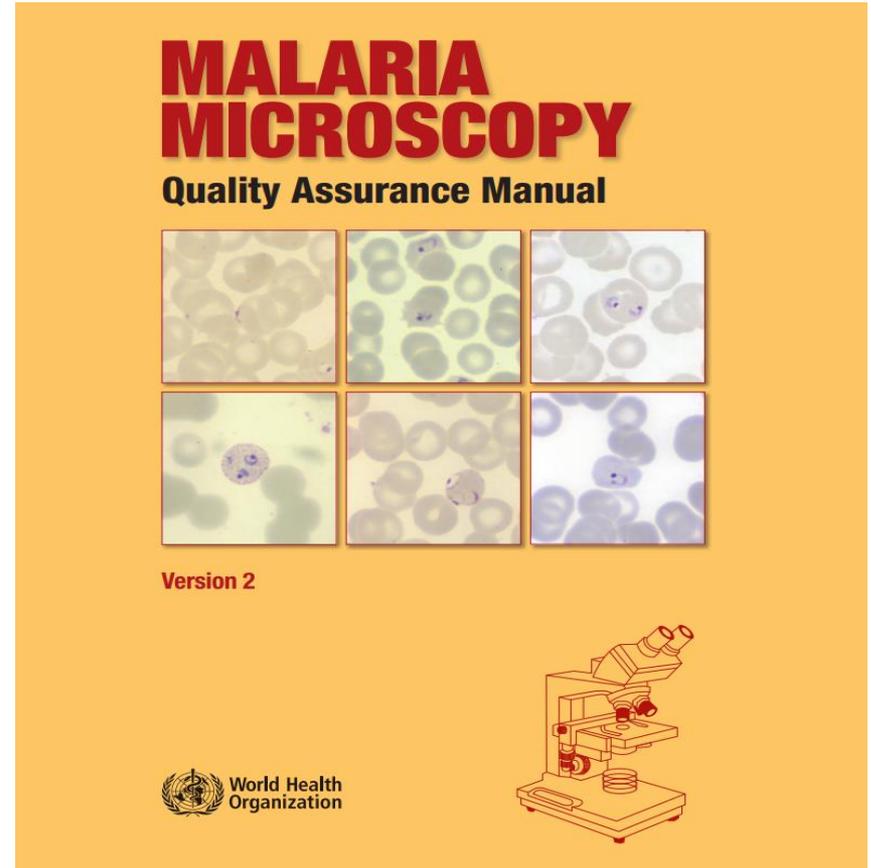
# Advocacy

WHO/CDS/EPR/LYO/2007.3

Policy and procedures of the

**WHO/NICD Microbiology  
External Quality  
Assessment Programme in  
Africa**

**Years 1 to 4  
2002-2006**



# Advocacy

WHO/HIS/SDS/2016.5

Establishing External Quality  
Assessment Programmes for  
Screening of Donated Blood  
for Transfusion-Transmissible  
Infections

Implementation Guide

Page 1 of 6 Original Research

## The World Health Organization African region external quality assessment scheme for anti-HIV serology

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A regional external quality assessment scheme (REQAS) for anti-HIV serology aimed to objectively assess reliability and quality of HIV testing processes in the African region. This involved the distribution of proficiency testing (PT) panels to participating laboratories from 2002 to 2010. During the survey period, this included 16 distributions of PT panels to 49 laboratories in 30 countries, and the overall average score during the nine-year survey period was 98.9%, with a frequency of accurate detection, of anti-HIV-1 and/or anti-HIV-2 antibodies in the PT panels, ranging from 93% to 100%. Problems highlighted included lack of human resources and frequent stock outs of test kits, reagents and consumables for routine HIV testing. The design of the REQAS allowed appraisal of the reliability of anti-HIV serological testing methods utilised by laboratories for clinical assessment of patients and/or surveillance programmes. The REQAS was able to demonstrate that laboratories participating in the REQAS performed well and sustained their participation in the scheme. This bodes well for clinical diagnosis, surveillance and training activities at these reference laboratories.

### Introduction

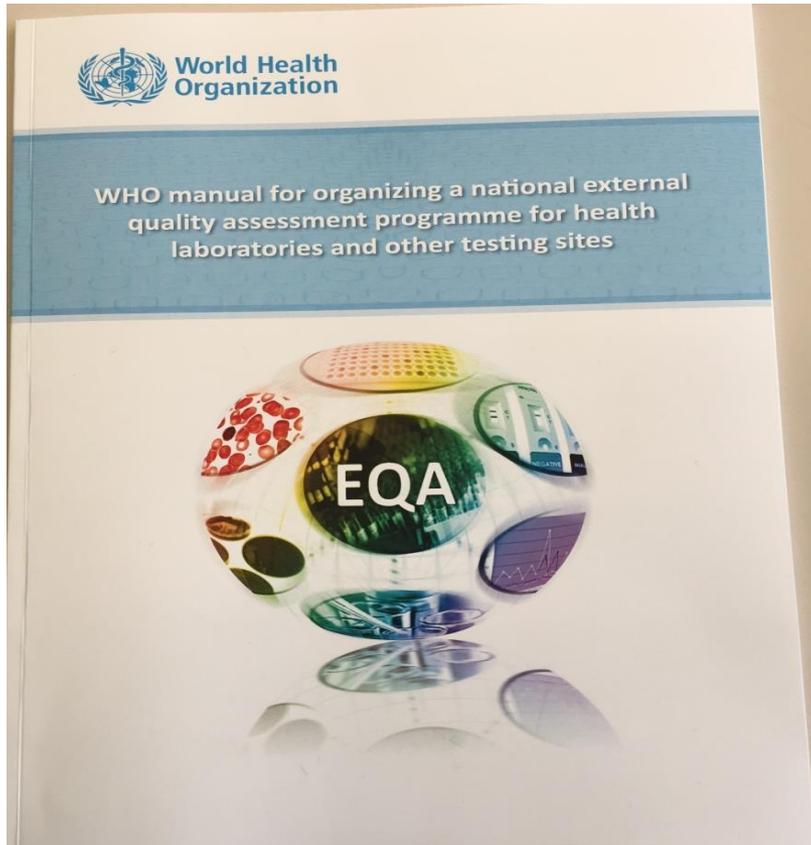
Since the 2001 United Nations General Assembly 26th Special Session (UNGASS) declaration of commitment for access to treatment care and support services for people living with HIV and/or AIDS, there has been an unprecedented scaling up of integrated and comprehensive services for diseases of public health importance in the African region ([www.UNAIDS.org](http://www.UNAIDS.org))<sup>1</sup>. As laboratory and non-laboratory testing for HIV, TB and malaria is one of the main entry points of access to prevention and support services, accurate and reliable laboratory results are essential for

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# The WHO EQA manual



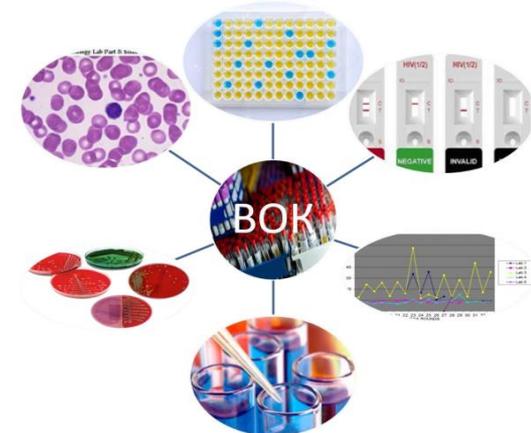
Based on ISO/IEC 17043:2010.

Группа ВОЗ по  
предварительной  
квалификации:  
ДИАГНОСТИКА



Всемирная организация  
здравоохранения  
Европейское региональное бюро

Руководство ВОЗ по организации  
национальной программы внешней оценки  
качества в лабораториях системы  
здравоохранения и других пунктах  
тестирования



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# The WHO manual

- Describes strategic managerial, financial, technical and scientific aspects to be considered when establishing a national EQA programme
- The scope: All WHO Member States, with a focus on developing countries
- The intended audience includes Ministries of health, programme managers, laboratory managers, testing personnel and other implementing partners and EQA providers.



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- 13. **Monitoring and evaluating the programme**



# Considerations for establishing national EQA Programme

## ● Advantages

- Improve PT samples availability, integrity, appropriateness
- More affordable in the long run
- Enable provision of better support to failing labs
- In-country capacity building: sample preparation, data analysis
- Provide opportunity to increase scope and coverage

## ● Challenges

- Initial high cost
- Preparation of challenging PT samples (CD4)
- Small number of labs



# Chapter 7&8

## Proficiency test items

- Requirements of proficiency test items
  - as similar as possible to patient specimens;
  - homogenous, as indicated by **homogeneity testing**;
  - **stable** at least for the PT round turnaround time;
  - **safe**;
  - **negative for infectious agents** unless specifically required for the PT round;
  - where applicable, **ready for use** with a pierceable septum;
  - **sterile**, except for specific instances such as microbiological PT rounds;
  - **acceptable** matrix, homogeneity and stability properties
- Establish to mechanism to
  - collect and characterize the PT item
  - Comparison of EQA materials from available sources
- Ensure stability during transportation

# Chapter 8

## Preparation of specific EQA test items

- Cover broad consideration when preparing specific EQA items
  - Haematology
  - Bacteriology
  - Parasitology
  - Clinical chemistry
  - Serology
  - Nucleic acid testing
  - Tissue based pathology
  - CD4 testing



## In vitro diagnostics and laboratory technology

[In vitro diagnostics and laboratory technology](#)

[Prequalification of IVDs and medical devices](#)

[Procurement of in vitro diagnostics](#)

[Post-market surveillance](#)

[Quality assurance](#)

[Guidance and training](#)

[Country projects](#)

### Quality assurance

The maintenance of a quality management system is crucial to a laboratory for providing the correct test results every time.

#### Quality assurance

Important elements of a quality management system include:

- Documentation
- Standard Operating Procedures (SOP's)
- Quality Control samples
- External Quality Assessment Scheme

#### Quality control

Are procedures used in each assay to assure a test run is valid and results are reliable:

- Kit Controls
- Quality Control Samples

#### External quality assessment schemes (EQAS)

Aims to analyse the accuracy of the entire testing process from receipt of sample and testing of sample to reporting of results (*also known as proficiency testing*)

- [WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites](#)



### EMERGENCY USE ASSESSMENT AND LISTING (EUAL) PROCEDURE

- [Zika Virus Disease](#)
- [Ebola Virus Disease](#)

### Related Topics

- [WHO list of prequalified in vitro diagnostic products](#)
- [Status of active applications to the prequalification of in vitro diagnostics](#)
- [Complaints and Product Alerts](#)
- [Streamlining of the Prequalification of Diagnostics](#)
- [WHO Prequalification of Male Circumcision Devices](#)
- [Procurement of in vitro diagnostics](#)
- [HIV incidence assay working group](#)
- [Information resources](#)

### Recent Highlights

- <http://apps.who.int/iris/bitstream/10665/250117/1/9789241549677-eng.pdf?ua=1>
- [http://www.euro.who.int/\\_data/assets/pdf\\_file/0003/339366/20170426\\_WHO-EQA-Manual\\_v16-08-29\\_rus-2.pdf](http://www.euro.who.int/_data/assets/pdf_file/0003/339366/20170426_WHO-EQA-Manual_v16-08-29_rus-2.pdf)



# Support to countries

- Collaboration with WCC

- Serology: HIV, HBsAg and HCV (NRL Melbourne, Dakar, Senegal)
- Haematology & Coagulation (UKNEQAS), Watford General Hospital, UK
- Biochemistry (University Hospitals Birmingham)
- CD4 (Health Canada)
- Blood and stool parasites (AMREF, Kenya)
- Public Health pathogens (NICD, WHO Lyons Office)

- TB Supranational Reference Laboratory Network

- Provide standardized quality assessment for microscopy, culture, drug susceptibility testing of *M. tuberculosis*, and molecular methods as needed



# Looking in the future

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- More languages



# Contacts



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