

## List of relevant guidance on quality assurance and quality monitoring of diagnostic products for information to PRs of Global Fund grant-funded programmes

### General

Topic	Document (click on link to open)	Description
Quality Assurance systems	WHO. <a href="#">A Model Quality Assurance System for Procurement Agencies</a>	Interagency guidelines, containing recommendations for quality assurance systems, including prequalification of products and manufacturers, purchasing, storage and distribution.
Reporting of adverse events	GHTF. Medical Devices Post Market Surveillance: <a href="#">Global Guidance for Adverse Event Reporting for Medical Devices</a> , 30 November 2006	A global model which provides guidance on the type of adverse events associated with medical devices that should be reported by manufacturers to a national competent authority.
Review of postmarket surveillance requirements	GHTF <a href="#">Review of current requirements on postmarket surveillance</a> 1 February 2006	A review of current procedures for postmarket surveillance by national regulatory authorities.
Manual for procurement of diagnostics and related laboratory items and equipment	WHO. (In preparation)	Interagency guidelines containing recommendations for procurement process specifically related to diagnostics and laboratory consumables and equipment.
Laboratory equipment maintenance	WHO <a href="#">Maintenance manual for laboratory equipment, 2nd edition</a>	For staff working in health laboratories. Gives technical requirements regarding installation, use and maintenance of various types of laboratory equipment.
Basic Techniques for a Health Laboratory	WHO <a href="#">Manual of Basic Techniques for a Health Laboratory</a>	For staff working in health laboratories. Gives technical information on sampling of specimens for laboratory investigation, identification of bacteria and testing of antimicrobial resistance.
Laboratory Biosafety Manual	WHO <a href="#">Laboratory Biosafety Manual</a>	A practical guide to the safe and accurate performance of basic laboratory techniques. Intended for use by laboratory technicians working in peripheral-level laboratories in developing countries.

Requirements for medical laboratories	ISO15189:2007 <a href="#">ISO 15189:2007 Medical laboratories - particular requirements for quality and competence</a>	International standard for use by laboratory staff in medical laboratories to develop their quality management systems and assess their own competence, and for use by accreditation bodies in confirming or recognizing the competence of medical laboratories.
Quality standards for health laboratory	WHO <a href="#">Quality Standards for Health Laboratories</a>	Implementation of a novel approach to achieving quality standards in Thailand

## Malaria

Some principles are also applicable to other diagnostic products

Topic	Document (click on link to open)	Description
Good procurement practices	WHO. Good procurement practices for malaria Rapid Diagnostic Tests (In preparation)	
Transport, storage	WHO/FIND/TDR/RBM - Purchasing and Using RDTs: <a href="#">Transport and Storage of Malaria RDTs</a>	On-line guidance and links to two manuals:  <a href="#">Transporting, Storing and Handling Malaria Rapid Diagnostic Tests at Central and Peripheral Storage Facilities</a> <a href="#">Transporting, Storing and Handling Malaria Rapid Diagnostic Tests in Health Clinics</a>
Malaria Microscopy	WHO Regional Office for the Western Pacific. <a href="#">Malaria microscopy quality assurance manual</a> - Version 1, 2009	Manual aiming to assist managers of national malaria control programmes and laboratory services to develop and maintain a sustainable malaria microscopy QA programme.
External Quality Assurance (EQA)	WHO/PHIL/CDC/IUATLD/KNCV /RIT. <a href="#">External Quality Assessment for AFB Smear Microscopy.</a>	Manual of guidelines and methods to assess the quality and reliability of laboratory services
Malaria RDT Lot-testing	WHO/FIND/TDR/RBM - Malaria Rapid Diagnostic Tests: <a href="#">RDT Lot Testing Programme</a>	Online guidance on lot-testing, and links to request form, report forms and other related information.
RDTs - Instructions and Training	WHO/FIND/TDR/RBM - <a href="#">Purchasing and Using RDTs: RDT Instructions and Training</a>	Training and instructions for RDTs. WHO-FIND generic training manuals and job-aids.

## HIV

Topic	Document (click on link to open)	Description
Use and selection of technology type	WHO/CDC - <a href="#">HIV Rapid Testing Training package</a> . Including: <a href="#">Guidelines for assuring the accuracy and reliability of HIV Rapid Testing: Applying a Quality System Approach-2005</a> .	Manual on policy development, planning, and implementation of HIV rapid testing, for government health officials, programme managers and testing personnel with or without laboratory training.
HIV surveillance	WHO/CDC/UNAIDS - <a href="#">Guidelines for Using HIV Testing Technologies in Surveillance: Selection, Evaluation and Implementation</a> - 2009 Update	Technical guidelines for HIV surveillance coordinators and laboratory professionals involved in HIV testing for surveillance purposes in low- and middle-income countries.
Operational and performance characteristics of HIV assays	WHO <a href="#">Report 16 HIV Assays - simple/rapid</a> <a href="#">Report 15 HIV Assays - antigen/antibody ELISAs</a> <a href="#">Report 14 HIV Assays - simple/rapid</a> <a href="#">Report 12 HIV Assays - whole blood simple/rapid</a>	Technical reports of the operational and performance characteristics of commercially available HIV assays.
HIV testing and recommendations for re-testing	WHO <a href="#">Delivering HIV test results and messages for re-testing and counselling in adults</a>	Technical guidelines to explain when HIV re-testing should and should not be recommended.
HIV testing strategies	WHO <a href="#">Revised recommendations for the selection and use of HIV antibody tests</a>	Technical guidelines to recommend testing strategies to maximize accuracy while minimizing cost. Which strategy is most appropriate will depend on the objectives of the testing and the prevalence of HIV in the population.
Maputo Declaration and meeting report	WHO/AFRO, CDC <a href="#">Maputo Declaration on strengthening laboratory systems</a> <a href="#">Consultation on technical and operational recommendations for clinical laboratory testing harmonization and standardization</a> <a href="#">Annex C</a> <a href="#">Annex D-E</a> <a href="#">Annex F-G</a> <a href="#">Annex H</a>	Meeting report that details technical recommendations on which laboratory tests need to be performed at each level of the laboratory network.
Improving quality of HIV testing and counselling services	WHO <a href="#">Handbook for improving HIV testing and counselling services</a>	Tool that can be used at any level of the health system in improve quality of services for HIV testing and counselling.