Global Fund Quality Assurance Policy for Diagnostics products: collaboration with WHO DLT
QA for health products financed by Global Fund

Global Fund Quality criteria
see Standard Terms and Conditions (v. 2010, under modification)

**Pharmaceuticals:**
QA policy (amended December 2010)

**Diagnostics:**
QA policy (approved December 2010)

**Insecticidal Nets:**
WHOPES standards

**Condoms:**
Procurement guidelines (WHO 2010)

Good Procurement Practices
Principal Recipients must procure all products in accordance with principles set out in the interagency guidelines

“A Model Quality Assurance System for Procurement Agencies”.
Increasing use of RDTs. Ex: Malaria

The number of RDTs funded by is likely to increase significantly in coming years. Vast majority of funding for RDTs comes from the GFATM.

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>PMI</td>
<td>3,470,000</td>
<td>4,840,526</td>
<td>10,744,800</td>
</tr>
<tr>
<td>WB</td>
<td>3,000,000</td>
<td>6,000,000</td>
<td>3,000,000</td>
</tr>
<tr>
<td>GFATM</td>
<td>59,183,853</td>
<td>79,678,832</td>
<td>91,244,184</td>
</tr>
<tr>
<td>government</td>
<td>519,387</td>
<td>765,531</td>
<td>4,625,961</td>
</tr>
<tr>
<td>others</td>
<td>5,397,491</td>
<td>5,424,692</td>
<td>4,747,579</td>
</tr>
</tbody>
</table>

Source: estimates by MMV and RBM October 2009
QA Policy for diagnostics: Background and development process

- Nov 2008 Request by the Board
  - Board requested to collaborate with WHO
  - 2009: review status of quality assurance for diagnostic products
  - proposed framework for policy development
  - 2010: draft QA Policy prepared by TAG
  - Partners Consultation: Draft QA Policy shared with >30 stakeholders
- December 2010:
  - The Board approved the quality assurance policy for diagnostic products (“QA Policy for Diagnostics”) as 14th December 2010, to be in force 1st March 2011
Quality Assurance Policy for Diagnostic Products

• **Scope of policy:**
  - All durable and non-durable In Vitro Diagnostic Products (IVDs),
  - Products not classified as IVDs, but important in grant-funded programs (microscopes, imaging equipment)

• **Clinical standards**
  - Ensure use of appropriate tests

• **Quality standards**
  - Ensure that tests are designed and manufactured to perform satisfactorily

• **Ensuring quality of use**
  - Ensure that tests are stored, distributed, monitored, and used in such a way that they perform satisfactorily
Selection of products types

- Product types must be selected in compliance with:
  - National guidelines
  Or
  - WHO guidance

- A technical justification should be provided if included in one of above guidance and not in the other
Quality standards for manufacturing sites

Diagnostic products must be manufactured at a site complying with the requirements of applicable ISO standards*:

• **ISO 13485:2003 for:**
  - In vitro diagnostics (e.g. RDTs, viral load and CD4)
  - Imaging equipment (e.g. X-ray machines)

• **ISO 9000 series** for products to which ISO 13485 does not apply: Microscopes

*Or an equivalent quality management system recognized by an authority member of GHTF
# Quality standards for HIV & malaria immunoassays only

<table>
<thead>
<tr>
<th>Required standard</th>
<th>Malaria RDTs</th>
<th>HIV RDTs, ELISA and WB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved by WHO after technical assessment, OR</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Assessed according to requirements of authorities member of GHTF*</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

The Global Fund can seek expert advice from WHO on procurement of needed products which do not meet either of the above standards.
Expert advice

The Board requests the Secretariat to work with the World Health Organisation (WHO) towards concluding an agreement under which WHO will manage the technical evaluation of diagnostic products, including, as relevant, the establishment of an Expert Review Panel for Diagnostics, as described in the QA Policy for Diagnostics.
Guidance for PRs

LISTS OF PRODUCTS
List of Malaria RDTs (WHO evaluations)

According to the Global Fund Quality Assurance Policy for Diagnostic Products (http://www.theglobalfund.org/en/procurement/policy), in force since 1st March 2011, grant funds may only be used to procure malaria RDTs if they have been:

- approved by the WHO Prequalification Programme (http://www.prequalification.org/)
- approved by the Malaria RDT EC (http://www.who.int/malaria/diagnostics/rdt-selection/rdt-selection_2012.pdf)
- approved by the WHO Prequalification Committee (http://www.who.int/malaria/diagnostics/rdt-selection/rdt-selection_2012.pdf)

The list below is an overview of malaria RDTs recommended for use after technical evaluation by the Malaria RDT EC (http://www.prequalification.org/) and WHO Prequalification Programme (http://www.who.int/malaria/diagnostics/rdt-selection/rdt-selection_2012.pdf), and should be used together with the WHO Information Note on Recommended Selection Criteria for Procurement of Malaria RDTs (http://www.who.int/malaria/diagnostics/rdt-selection/rdt-selection_2012.pdf). Products marked with an asterisk (*) have been found acceptable for use by Recipients.

The list is developed as a tool to assist Principal Recipients (PRs) of Global Fund grants to identify the status of malaria RDTs according to the Global Fund Quality Assurance Policy. The list is not exhaustive; PRs can procure product(s) not listed below as long as PRs demonstrate that the product is compliant with one of the above mentioned requirements. The list will be updated regularly based on evidence received by the Global Fund.

Disclaimer: The Global Fund does not endorse or warrant the fitness of any product on the list for a particular purpose. In addition, the Global Fund assumes no responsibility for any misstatement or omission from the list and directs Principal Recipients of Global Fund grants to conduct their own independent verification that the information on a given product on the list is accurate before relying on it to make a purchase order for that product, and to ensure that any purchase is in compliance with all the requirements of the Global Fund’s Quality Assurance Policy. The Global Fund does not warrant or represent that the product listed have obtained regulatory approval for use in any particular country of the world, or that their use is otherwise in accordance with the national laws and regulations of any country, including, but not limited to, intellectual property laws. The Global Fund disclaims any and all liability and responsibility for any injury, death, damage or loss of any kind whatsoever that may arise as a result of, or in connection with, the procurement, distribution and use of any product included in the list.

<table>
<thead>
<tr>
<th>Manufacturer Product Catalogue number</th>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Number of tests per kit</th>
<th>Shelf life (months)</th>
<th>Recommended storage temperature</th>
<th>Area of intended use: High transmission area, panel selection score ≥ 75%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 G0141</td>
<td>Casset Malaria HRP2/PR</td>
<td>Access Bio, Inc</td>
<td>60</td>
<td>24</td>
<td>4-30°C</td>
<td>All areas</td>
</tr>
<tr>
<td>2 G0101-3K</td>
<td>Casset Malaria HRP2/plHk/PT test</td>
<td>Access Bio, Inc</td>
<td>40</td>
<td>24</td>
<td>4-30°C</td>
<td>All areas</td>
</tr>
<tr>
<td>3 G01881</td>
<td>Casset Malaria HRP2/plHk/PT test</td>
<td>Access Bio, Inc</td>
<td>60</td>
<td>24</td>
<td>4-30°C</td>
<td>All areas</td>
</tr>
</tbody>
</table>
List of HIV Immunoassays (WHO evaluations)

Since 1999, WHO has performed assessments of commercially available diagnostics for HIV, hepatitis B, hepatitis C and Chagas disease. Up to 2006, this process was called the WHO Test Kit Evaluation programme, it was the predecessor of the WHO Prequalification of Diagnostics Programme. Currently, products meeting the following product selection criteria are eligible to participate in the WHO process for establishing a long term agreement (LTA) for procurement by WHO through a request for proposal (RFP).

The product selection criteria for HIV diagnostics are:

<table>
<thead>
<tr>
<th>Analyte</th>
<th>ELAs</th>
<th>SimpleWrap assays</th>
</tr>
</thead>
</table>
| HIV     | Sensitivity: ≥ 99%  
Specificity: ≥ 98% | Sensitivity: ≥ 99%  
Specificity: ≥ 99%  
Inter-reader variability ≤ 5% |


Shelf life
Products supplied should have a long maximum shelf life upon manufacture, where possible. The guaranteed minimum shelf life upon delivery is negotiated as part of the bidding process. As a minimum, at least 6 months shelf life remaining should be guaranteed up upon delivery to country.

For further information about this product list, contact by e-mail: diagnostics@who.int
## Quality of use

|----------------------|---------------------|---------------------------|

**A compilation of WHO guidance in website**

- PRs must follow WHO guidance for good practice in storage and distribution of diagnostic products.
- PRs must ensure that diagnostic products are only used by appropriately trained and qualified staff in adequate settings.
- PRs must use best efforts to:
  - participate in External Quality Assessment (EQA) programs.
  - organize calibration and maintenance of equipment.
  - arrange for systematic reporting of product defects.
  - Lot testing should be arranged for when WHO guidance and capacity exist for the specific product type.
Quality Assurance Information

Quality assurance refers to the management activities required to ensure that the medicines (and/or other health products) that reach patients are safe, effective and acceptable to the patient. These activities may include, but are not limited to, (pharmaceutical products) registration, pre-qualification and quality control.

We strongly encourage you to visit this site frequently and make sure to use the most recent version when considering the procurement options.

Procurement Practices to Assure Quality

In addition to the Global Fund’s existing polices for procurement practices, Principal Recipients must ensure that all pharmaceutical products are procured in accordance with the principles set out in the interagency guidelines "A Model Quality Assurance System for Procurement Agencies".

Compliance with National Regulations

Pharmaceuticals and other health products procured with Global Fund resources must at all times comply with national regulations and, where applicable, be authorized by the national drug regulatory authority in the country in which they are used, following its standard practices for registration (or other forms of authorization, such as authorizations for special use).

Pharmacovigilance

Pharmacovigilance (PV) is defined by the World Health Organization (WHO) as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems". Pharmacovigilance is of paramount importance for Global Fund-financed programs to enhance program effectiveness and the
DLT : technical Partner for The Global Fund

WHO Diagnostics and Laboratory Technology = key partner in policy development and implementation

• Developing countries: generally weak systems
• Lack of knowledge at country level: procurement officials.
• Lack of guidance in diverse aspects and difficulties on selecting products (performance, quality standards)
• Diagnostic market is very dynamic
Challenges

– Ensuring availability of information for more recent products
  • enabling uptake of improved products in a rationale way
  • Other critical categories: TB products …

– Ensuring critical parameters of quality are taken into account by countries
  • Selecting best product within a given type based on key parameters
  • Sensitivity, specificity, …
  • Other?

– Increase number of evaluated products
  • To ensure timely supplies
  • To ensure competition to increase availability and accessibility of assured quality products
DLT: technical Partner for The Global Fund

Increased collaboration between main partners
- Harmonization
- Unique message to manufacturers
- Decreased risk

Need for WHO guidance for PRs:
- Development of Quality Assurance systems
- Selection of products
- Ensuring quality of use
- Training