

## Quick Facts on Procuring Malaria Rapid Diagnostic Tests with Global Fund Grants

December 2011

### Background

1. WHO recommends that all suspected cases of malaria be confirmed with a diagnostic test prior to treatment, and new targets of universal access to malaria diagnostic testing have been set by Roll Back Malaria.
2. Malaria Rapid Diagnostic Tests (RDTs) are crucial to improve the diagnosis and management of malaria, especially where quality microscopy diagnosis cannot be provided.
3. A variety of RDTs for the detection of the different malaria antigens are available on the market; quality and performance might vary substantially among the different products. Ensuring the quality of RDTs is essential to ensure accurate diagnosis.
4. All Global Fund's Recipients must comply with the Quality Assurance Policy for Diagnostic Products<sup>1</sup> (QA Policy), in force since March 2011, including criteria to ensure the quality and adequate use of RDTs procured with Global Fund resources.

#### Global Fund Quality Assurance Policy for Diagnostic Products

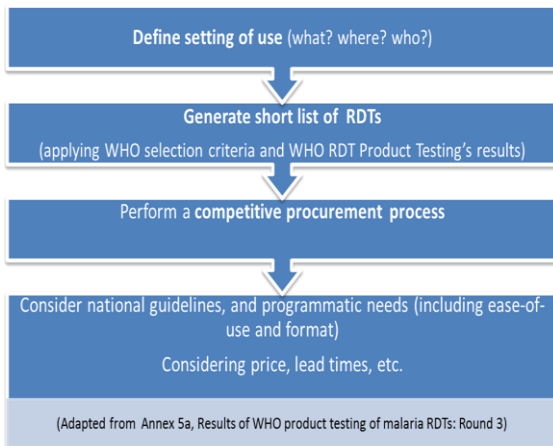
<b>(a) CLINICAL CRITERIA</b> Product types must be selected in compliance with: <ul style="list-style-type: none"><li>• National guidelines</li><li>• WHO guidance</li></ul>	<b>(b) QUALITY STANDARDS</b> <b>Manufacturing site for all products:</b> <ul style="list-style-type: none"><li>• compliant with ISO 13485 (except for microscopes for which ISO9000 applies)</li></ul> <p style="text-align: center;">+</p> <b>Product standards for Malaria RDTs:</b> <ul style="list-style-type: none"><li>• approved by WHO after technical assessment</li></ul>
<b>(c) MONITORING QUALITY AND ENSURING ADEQUATE USE</b> <ul style="list-style-type: none"><li>Adequately trained staff</li><li>Adequate storage and distribution</li><li>Lot testing</li><li>Reporting of failures</li></ul>	

### Selection of a short list of RDTs eligible for purchase

5. To select the appropriate type of RDTs for a given area, WHO-recommended selection criteria for procurement of malaria rapid diagnostic tests<sup>2</sup> need to be considered:
  - ✓ target parasite species and antigens,
  - ✓ panel detection score (considering the malaria transmission intensity in the area of intended use),
  - ✓ false-positive and invalid rates,
  - ✓ ease of use,
  - ✓ thermal stability.
6. In determining RDTs' compliance with WHO criteria above, Recipients should use the results of the WHO Malaria RDT Product Testing Programme<sup>3</sup>. In country-studies to determine performance (sensitivity/specificity) of the RDTs are not recommended by WHO as a primary basis for product selection<sup>4,5</sup>. However, ease of use assessments in local conditions may be highly relevant in informing procurement decisions within a short list of RDTs (see below 11.i).
7. To facilitate Recipients' selection of RDTs, and based on its QA Policy, the Global Fund maintains on its website a summary List of malaria RDTs<sup>6</sup> (identified by their **catalogue number-product code**): it includes products assessed by the WHO Malaria RDT Product Testing Programme and found to comply with WHO procurement criteria and, where available, by the complementary WHO Prequalification Programme for diagnostic products<sup>7</sup>.
8. Procurement of malaria RDTs should be in line with national malaria guidelines, and guided by programmatic needs such as training requirements for health workers, completeness of the kits, and ease of use. Previous experience in use of RDTs, and level of deployment in the country should also be taken into account.

## Procurement process

9. Once a short list of RDTs adequate for a given program is identified as described above, a competitive process should be run among the short-listed products.
10. Recipients should ask the manufacturer to disclose the manufacturing site in the tender process.
11. Additionally, other recommended information and specifications to be included in the tender request are:
  - a. stability data and shelf life;
  - b. delivery schedules and lead times (staggered delivery of products is recommended);
  - c. agreement for a sampling-agency to take samples for lot testing;
  - d. WHO-FIND lot testing results;
  - e. evidence of production capacity and long-term viability of manufacturer;
  - f. agreement for replacement of defective products;
  - g. description of individual test packaging (completeness of kits) and box sizes; and
  - h. instructions and information (package insert).



- i. For RDTs not previously used in the country, if deemed necessary, ask samples for local checking of ease-of-use, confirmation of appropriateness of all contents of the kit, and screening of major anomalies. This could help to determine which of a short-list of products is most appropriate for the technicians and situation of its intended use (guidance for such assessments is provided in Annex 5b, pg.105, Malaria Rapid Diagnostic Test Performance, Results of WHO product testing of malaria RDTs: Round 3). Alternatively, documentation on ease-of-use from other countries with similar conditions might be requested.



12. If considered relevant to avoid disruptions to malaria programmes, Recipients might continue to use a given RDT provided a competitive selection process had been performed within, at least, the previous 3 years, and the Recipient can submit to the Secretariat evidence of:
  - ✓ continued compliance of the product with the quality criteria defined in the Global Fund QA Policy ;
  - ✓ evidence of adequate performance in WHO-FIND Lot testing;
  - ✓ absence of reports of failure in the field.
13. When comparing the price of equivalent RDT products in a competitive process, the additional costs linked to the introduction of a new RDT not previously used in the country, if relevant, should be taken into account (re-training, or re-design of job aids). Expected additional costs must be compared against estimated procurement cost (considering the unit price of eligible RDTs) for the period of time until a new tender process will be performed (a maximum period of 3 years).

## Lot Testing

14. As the performance of a given RDT may vary between lots over time, production lots should be checked through **lot-testing** as part of good procurement practices, using the WHO-FIND Lot Testing of Malaria Rapid Diagnostic Tests<sup>8</sup> and its recognized laboratories. Pre-shipment testing is

generally preferred to avoid the arrival of substandard products in a country and consequent disposal or replacement. At least 2 weeks should be foreseen from sampling at manufacturing site to reporting of test results.

15. If pre-shipment lot testing has not been performed, testing of samples delivered to the central stores is recommended, using the same model than the pre-shipment lot testing described above.

### Transport and storage requirements

16. Malaria RDTs can be degraded by exposure to high temperatures, freezing and moisture. Always check product-specific instructions on temperature restrictions for storage. Transport, storage and in-country distribution of RDTs should be performed in temperature-controlled means to ensure that the temperatures remain within the manufacturer's specified limits at any time.

### Ensuring adequate use

17. Training materials and instructions (job-aids) should be developed, appropriate to the language and literacy of users and using generic templates as much as possible<sup>9,10</sup>. Adequate supervision of technicians is paramount to monitor the correct preparation and use of RDTs and the correct interpretation of its result, ensuring blood safety at any time.

### Further guidance

18. This briefing note lists some key points to be considered for the procurement of RDTs with Global Fund grants. It is strongly recommended that Recipients refer to WHO specific guidance on procurement of RDTs: [Good Practices for selecting and procuring rapid diagnostic tests for malaria](#), 2011



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<sup>1</sup> The Global Fund, Quality Assurance Policy for Diagnostic Products

([http://www.theglobalfund.org/Documents/psm/PSM\\_QADiagnostics\\_Policy\\_en/](http://www.theglobalfund.org/Documents/psm/PSM_QADiagnostics_Policy_en/))

<sup>2</sup> WHO Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests

([http://www.who.int/malaria/diagnosis\\_treatment/diagnosis/RDT\\_selection\\_criteria.pdf](http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf))

<sup>3</sup> WHO Malaria RDT Product Testing Programme. Full reports of Rounds 1, 2 and 3

([http://www.wpro.who.int/sites/rdt/who\\_rdt\\_evaluation/call\\_for\\_testing\\_round3.html](http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/call_for_testing_round3.html))

<sup>4</sup> WHO Good Practices for selecting and procuring rapid diagnostic tests for malaria, WHO Global Malaria Programme, 2011

(<http://www.who.int/malaria/publications/atoz/9789241501125/en/index.html>)

<sup>5</sup> WHO Universal Access to Malaria Diagnostic Testing: an operational manual, 2011

([http://whqlibdoc.who.int/publications/2011/9789241502092\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241502092_eng.pdf))

<sup>6</sup> The Global Fund, List of Rapid Diagnostic Test Kits for Malaria classified according to the Global Fund Quality Assurance Policy

([http://www.theglobalfund.org/Documents/psm/PSM\\_QADiagnostics\\_Malaria\\_list/](http://www.theglobalfund.org/Documents/psm/PSM_QADiagnostics_Malaria_list/))

<sup>7</sup> WHO List of prequalified products ([http://www.who.int/diagnostics\\_laboratory/evaluations/PQ\\_list/en/index.html](http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/index.html))

<sup>8</sup> WHO/FIND Lot Testing of Malaria Rapid Diagnostic Tests

([http://www.wpro.who.int/sites/rdt/who\\_rdt\\_evaluation/lot\\_testing.htm](http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/lot_testing.htm))

<sup>9</sup> FIND, Training Materials for Malaria RDTs ([http://www.finddiagnostics.org/programs/malaria/find\\_activities/rdt-job-aids/](http://www.finddiagnostics.org/programs/malaria/find_activities/rdt-job-aids/))

<sup>10</sup> WHO, RDTs Instructions and Training ([http://www.wpro.who.int/sites/rdt/using\\_rdt/training](http://www.wpro.who.int/sites/rdt/using_rdt/training))