

**WHO Global Malaria Programme**  
**Information note on recommended selection criteria for**  
**procurement of malaria rapid diagnostic tests (RDTs)**  
- 12 April 2012 -

In view of the increasing demand of countries to scale-up malaria diagnostics following the large-scale introduction of expensive antimalarial medicines, and the decreasing malaria trends in many countries, there is a need for guidance in the selection of malaria rapid diagnostics that meet international quality standards. This WHO note aims to provide information on both the criteria which have been recommended for and additional considerations which play a role in the procurement of malaria rapid diagnostic tests.

### WHO policy on malaria diagnosis

WHO recommends parasitological confirmation of malaria through quality assured diagnosis in all settings before treatment is started<sup>1</sup>. Treatment solely on the basis of clinical suspicion should only be considered when a parasitological diagnosis is not accessible, i.e. not available within two hours of patients presenting for treatment. Prompt diagnostic confirmation of malaria can be achieved through quality microscopy or quality rapid diagnostic tests detecting *Plasmodium falciparum* and/or *Plasmodium vivax* infections. In most countries both diagnostic methods are needed, as microscopy and RDTs often play different roles according to the clinical situations or the setting.

### WHO Malaria RDT Product Testing Programme

The heterogeneous diagnostic performance of more than 200 malaria RDTs currently available in the market can undermine the confidence of health professionals in the accuracy of these tests. The WHO Malaria RDT Product Testing Programme, coordinated by WHO/TDR and the Foundation for Innovative New Diagnostics (FIND) and executed in collaboration with US Centers for Disease Control and Prevention (CDC), provides comparative data on the performance of various RDTs available in the market to assist in procurement. Since 2008, 120 products have been evaluated over three rounds of WHO Malaria RDT Product Testing. This encompasses 95 unique products and 22 product resubmissions (see Annex 1).

Each round of product testing begins with an invitation to all companies manufacturing under "ISO-13485: Medical devices - Quality management systems - Requirements for regulatory process" to submit up to 2-3 different RDTs for evaluation. The RDTs are evaluated against panels of cultured *P. falciparum* parasites (n=20), panels of patient-derived *P. falciparum* (n~100) and *P. vivax* (n~40) parasites, and a parasite-negative panel (n=100). The panel detection score (PDS)<sup>2</sup>, key parameter of the assessment, is thus not a measure of RDT clinical sensitivity or positivity rate against the panel but rather a combined measure of positivity rate along with inter-test and inter-lot consistency. In addition, thermal stability of the products is assessed after 2 months of storage at elevated temperatures (35°C, 45°C) and 75% humidity, and ease of use is also evaluated. The full report of results of all Rounds 1, 2, and 3 is available at:

<http://www.who.int/malaria/publications/atoz/9789241502566/en/index.html>.

<sup>1</sup> The WHO Guidelines for the treatment of malaria, 2nd edition 2010, are available at: [http://whqlibdoc.who.int/publications/2010/9789241547925\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf)

<sup>2</sup> The term 'panel detection score' (PDS) is a composite index of test positivity as well as of inter-test and inter-lot consistency in performance. Panel detection score is not equivalent to sensitivity - see page 18 of the report of the Round 2 WHO malaria RDT product testing for a detailed description of this parameter ([http://whqlibdoc.who.int/publications/2010/9789241599467\\_eng.pdf](http://whqlibdoc.who.int/publications/2010/9789241599467_eng.pdf)).

## WHO selection criteria for the procurement of RDTs

Experts convened at the Inaugural Meeting of the Malaria Policy Advisory Committee (MPAC), held in Geneva in early 2012, updated the WHO recommendations for the procurement of RDTs. Products should be selected in line with the following set of criteria, based on the results of the assessment of the WHO Malaria RDT Product Testing Programme<sup>3</sup>:

- (A) For the detection of *Plasmodium falciparum* (Pf) in all transmission settings the **panel detection score (PDS)** against Pf samples should be at least 75% at 200 parasites/ $\mu$ L.
- (B) For the detection of *Plasmodium vivax* (Pv) in all transmission settings the **panel detection score (PDS)** against Pv samples should be at least 75% at 200 parasites/ $\mu$ L.
- (C) The **false positive rate** should be less than 10%.
- (D) The **invalid rate**<sup>4</sup> should be less than 5%.

## **FIND's web-based interactive guide for the selection of malaria RDTs**

Based on the results of Rounds 1-3 of the WHO Malaria RDT Product Testing Programme, FIND has developed a web-based interactive guide which allows to select suitable malaria RDTs on the basis of the following parameters: i) target malaria species, ii) minimum panel detection score for *P. falciparum* at 200 and 2000 parasites/ $\mu$ L, iii) minimum panel detection score for *P. vivax* at 200 and 2000 parasites/ $\mu$ L, iv) maximum false positive rate, v) maximum invalid rate, vi) test format and vii) heat stability. This guide is available at:

[http://www.finndiagnostics.org/programs/malaria/find\\_activities/product\\_testing/malaria-rdt-product-testing](http://www.finndiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing).

## Additional considerations relevant for procurement of malaria RDTs

### **Stability requirements at temperatures of intended storage, transport and use**

RDTs submitted to WHO for malaria RDT product testing are evaluated for positivity against a single cultured *P. falciparum* isolate at 200 parasites/ $\mu$ L at baseline and after 60 days of incubation at 35°C and 45°C. In this regard, it is recommended to select RDTs with high thermal stability for areas with very high temperatures.

### **Ease of use and training requirements for the health workers**

RDTs submitted to WHO for malaria RDT product testing are also evaluated for blood safety, instruction quality, number of steps, time to results, blood transfer device, format and kit completeness<sup>11</sup>. Cassettes and cards are easier to use than dipsticks. For reasons of blood safety, kits that include lancets and alcohol swabs are preferred over kits which do not contain these items. Dipsticks are more suitable for settings with a laboratory facility.

<sup>3</sup> The full report of the Round 3 of WHO/TDR/FIND/CDC malaria RDT Product Testing Programme is available at: <http://www.who.int/tdr/publications/documents/rdt3.pdf>.

<sup>4</sup> Proportion of tests deemed invalid, i.e. without visible control band.

## **Price**

After having considered all of the above factors, good procurement practice requires that the price be taken into account.

## **Programmatic needs**<sup>5</sup>

The aim of this note is not to recommend to national health authorities to immediately replace with new tests the malaria RDTs which are already being deployed on a large scale. The diagnostic performance of RDTs in the field is dependent on all the parameters listed above, as well as on the effectiveness of training and supervision and on the functioning of the supply management system. Particularly for programmes that are already implementing RDTs on a large-scale, the continued deployment of the currently used tests may be appropriate until a decrease in malaria transmission triggers the need for RDTs with better performance in detecting low-level parasitaemia. Plans to replace RDTs should be developed carefully, taking into consideration the training and supervision requirements to support the introduction of the new RDTs, as well as the production capacity and expected lead time for deliveries from the suppliers of the new RDTs.

For a comprehensive guide to procurement of malaria RDTs extending beyond selection criteria see the WHO manual on *Good practices for selecting and procuring rapid diagnostic tests for malaria*<sup>6</sup>. This manual also includes practical advice on quantification, budgeting, tender technical specifications, management of tenders and contracts, supply management up to the receipt of goods at port of entry, monitoring of supplier performance and managing product variations.

## **WHO-FIND Lot Testing Programme**

As the performance of individual products is likely to vary between lots over time, WHO recommends that all RDT production lots be checked, either pre- or post-shipment, through a lot-testing centre collaborating with the WHO-FIND Malaria RDT Product Testing Programme, as part of good procurement practice. Currently, this service is free of charge through WHO-FIND's two affiliated laboratories<sup>7</sup>. Full information on WHO recommended procedures for RDT lot testing are available at: [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).

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<sup>5</sup> This section is based on advice by WHO/GMP secretariat and not on recommendations of experts convened by a WHO Technical Consultation.

<sup>6</sup> The WHO manual on *Good practices for selecting and procuring rapid diagnostic tests for malaria*, Geneva, World Health Organization, 2011, is available at: [http://whqlibdoc.who.int/publications/2011/9789241501125\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf).

<sup>7</sup> The Research Institute for Tropical Medicine (RITM), Muntinlupa City, The Philippines, and the Institut Pasteur du cambodge (IPC), Phnom Penh, Cambodia.

## Annex 1: Performance of Malaria RDTs in Rounds 1-3 of WHO Malaria RDT Product Testing

The table of results reproduced below is extrapolated from the Table S1, published in the Results of WHO Malaria RDT Product Testing: Summary Rounds 1-3 (available at <http://www.who.int/tdr/publications/documents/rdt3.pdf>), listing the tested products in alphabetical order by brand name, catalogue number and manufacturer. To this list, the above WHO-recommended criteria for RDT procurement have been applied. Using the results of WHO Malaria RDT Product Testing Programme Rounds 1-3 as the basis, a green box indicates that the corresponding recommended criterion has been met, whereas a white box indicates that this criterion has not been met.

### *Disclaimer:*

*The list below does not in any way imply an endorsement, certification, warranty of fitness or recommendation by WHO of any company or product for any purpose, and does not imply preference over products of a similar nature that are not mentioned. WHO furthermore does not warrant that: (1) the list is complete and/or error free; and/or that (2) the products listed are of acceptable quality, have obtained regulatory approval in any country, or that their use is otherwise in accordance with the national laws and regulations of any country, including but not limited to patent laws. Inclusion in the list does not furthermore imply any approval by WHO of the products in question (which is the sole prerogative of national authorities).*

*The list is not an exhaustive list of malaria RDTs. The list reflects those products which have been submitted for evaluation in Rounds 1-3 of the WHO Malaria RDT Product Testing Programme (full report available at: <http://www.who.int/tdr/publications/documents/rdt3.pdf>). Using the results of Rounds 1 -3 as the basis, the criteria recommended for RDT procurement by WHO have been applied to this list.*

*The fact that certain products are not included in the list means that they have not or not yet been submitted for evaluation in the WHO Malaria RDT Product Testing Programme and does not indicate anything in respect of such products' performance.*

*WHO will not accept any liability or responsibility whatsoever for any injury, death, loss, damage, or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and use of any product whatsoever included in the list.*

*This list may not be used by manufacturers and suppliers for commercial or promotional purposes.*

### **Performance of malaria RDTs in Rounds 1-3 of WHO Malaria RDT Product Testing Programme**

Performance criteria:

**A:** *P. falciparum* panel detection score  $\geq$  75% at 200 parasites/ $\mu$ l

**B:** *P. vivax* panel detection score  $\geq$  75% at 200 parasites/ $\mu$ l

**C:** False positive rate < 10%

**D:** Invalid rate < 5%

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
<b>Pf only</b>								
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	√	Cassette		N/A		
Advanced Quality™ Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.		Cassette		N/A		
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.		Card		N/A		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote, Inc.		Cassette		N/A		
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.		Cassette		N/A		
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.		Cassette		N/A		
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	√	Cassette		N/A		
Core™ Malaria Pf	MAL-190020	Core Diagnostics		Cassette		N/A		
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems		Cassette		N/A		
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems		Dipstick		N/A		
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.		Cassette		N/A		
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.		Cassette		N/A		
Hexagon Malaria	58051	Human GmbH		Cassette		N/A		
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.		Card		N/A		

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	✓	Cassette		N/A		
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex		Cassette		N/A		
Immunoquick Malaria Falciparum	0502_K25	Biosynex		Dipstick		N/A		
Malaria <i>Plasmodium falciparum</i> Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.		Cassette		N/A		
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd		Cassette		N/A		
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	✓	Cassette		N/A		
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	✓	Cassette		N/A		
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.		Cassette		N/A		
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	✓	Cassette		N/A		
Paracheck® Pf Device- Rapid test for P. falciparum Malaria Ver. 3	30301025	Orchid Biomedical Systems	✓	Cassette		N/A		
Paracheck® Pf Dipstick- Rapid test for P. falciparum Malaria Ver. 3	30302025	Orchid Biomedical Systems	✓	Dipstick		N/A		
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	✓	Cassette		N/A		
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	✓	Dipstick		N/A		
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) <sup>k</sup>	05FK90	Standard Diagnostics Inc.		Cassette		N/A		
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.		Cassette		N/A		
<b>Pf and Pan</b>								
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.		Cassette				
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.		Card				
Binax Now Malaria Test	IN660050	Inverness Medical Innovations, Inc.		Card				

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote, Inc.		Cassette				
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, Inc.		Cassette				
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131	Access Bio, Inc.		Cassette				
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, Inc.		Cassette				
CareStart™ Malaria Screen	GO231	Access Bio, Inc.		Cassette				
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	√	Cassette				
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	√	Cassette				
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems		Cassette				
First Response® Malaria pLDH/HRP2 Combo Test	I16FRC30	Premier Medical Corporation Ltd.	√	Cassette				
FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	Unimed International Inc.		Cassette				
Hexagon Malaria Combi	58024	Human GmbH		Cassette				
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.		Card				
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.		Card				
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	√	Cassette				
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics		Cassette				
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex		Cassette				
Immunoquick Malaria +4	0506_K25	Biosynex		Dipstick				
Malaria P.F/Vivax	17211OP-25	Diagnostics Automation/ Cortez Diagnostics, Inc		Cassette				
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH		Cassette				

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	✓	Cassette				
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.		Cassette				
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	✓	Cassette				
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd		Cassette				
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd		Cassette				
One Step Malaria Antigen Strip	820-1	IND Diagnostic Inc.		Dipstick				
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	✓	Dipstick				
OnSight™ – ParaQuick (Pan, Pf) Test	536-25DB	Amgenix International, Inc.		Cassette				
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.		Cassette				
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad		Hybrid				
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd		Dipstick				
Parahit-Total Device Rapid test for P. falciparum and Pan malarial species	25989	Span Diagnostics Ltd.		Cassette				
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems		Cassette				
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.		Dipstick				
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	✓	Cassette				
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	✓	Cassette				
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.		Cassette				
<b>Pf and Pv</b>								
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.		Cassette				

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.		Card				
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.		Cassette				
CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.		Cassette				
CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.		Cassette				
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics		Cassette				
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems		Cassette				
Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	Zephyr Biomedicals		Cassette				
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.		Cassette				
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.		Cassette				
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd		Cassette				
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.		Cassette				
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	√	Cassette				
SD BIOLINE Malaria Ag Pf/Pv	05FK80	Standard Diagnostics, Inc.		Cassette				
<b>Pf, Pv and Pan</b>								
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics		Cassette				
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems		Cassette				
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.		Cassette				
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals		Cassette				

Product	Catalogue* number	Manufacturer	Re- tested product	RDT format	Performance criteria			
					A	B	C	D
<b>Pan only</b>								
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.		Cassette				
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.		Cassette				
Clearview® Malaria pLDH	70884025	Organics Ltd. (Inverness Medical Innovations)	✓	Cassette				
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems		Cassette				
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.		Cassette				
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.		Cassette				
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.		Cassette				
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	✓	Cassette				
<b>Pv only</b>								
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.		Cassette	N/A			

\* Some production may include different catalogue numbers for different box sizes; contact manufacturers for detailed information.

N/A Results not available

Pan All Plasmodium species

Pf *Plasmodium falciparum*

Pv *Plasmodium vivax*