



Information note on recommended selection criteria for procurement of malaria rapid diagnostic tests

September 2014¹

There is increasing demand for countries to improve malaria diagnosis in view of wide-scale introduction of expensive antimalarial medicines and the decreasing malaria trends in many countries. Therefore, guidance is required for selecting rapid diagnostic tests (RDTs) for malaria that meet quality standards. The aims of this WHO information note are to list the criteria recommended for selecting tests and to provide an overview of additional considerations in the procurement of malaria RDTs.

WHO policy on malaria diagnosis

WHO recommends parasitological confirmation of malaria in all settings by a quality-assured diagnosis before treatment is started.² Treatment solely on the basis of clinical suspicion should be considered only when a parasitological diagnosis is not available within two hours of presentation of a patient for treatment. A diagnosis of malaria can be confirmed rapidly by good-quality microscopy or with a good-quality malaria antigen-detecting RDT for *Plasmodium falciparum* and non-falciparum infections. In most countries, both diagnostic methods are required, as microscopy and RDTs often play different roles, depending on the clinical situation or the setting.³

WHO malaria RDT product testing programme

Product evaluation

The heterogeneous diagnostic performance of the more than 200 malaria RDTs currently available on the market can undermine the confidence of health professionals in the accuracy of these tests. The WHO malaria RDT product testing programme, coordinated by the Global Malaria Programme and the Foundation for Innovative New Diagnostics (FIND) and executed in collaboration with the United States Centers for Disease Control and Prevention, provides comparative data on the performance of the RDTs available on the market to guide procurement. Since 2008, 210 products have been evaluated in five rounds of product testing, comprising 147 unique products and 42 product resubmissions (see Annex 1). Each round of product testing begins with an invitation to all companies that manufacture products under ISO-13485 (Medical devices—Quality management systems—Requirements for regulatory process) to submit RDTs for evaluation. The submitted RDTs are evaluated against panels of 20 low- and high-density cultures of *P. falciparum* parasites, about 100 panels of patient-derived *P. falciparum*, about 35 panels of *P. vivax* parasites and a panel of 100 parasite-negative cultures. The main measure of performance is the panel detection score,⁴ which is measured separately for each RDT

1. This information note on recommended selection criteria for procurement of malaria rapid diagnostic tests replaces earlier versions released between 2009 and 2012.
2. World Health Organization. *WHO guidelines for the treatment of malaria*. Second edition. Geneva; 2010 (http://whqlibdoc.who.int/publications/2010/9789241547925_eng.pdf).
3. World Health Organization. *Universal access to malaria diagnostic testing – an operational manual*. Geneva; 2011 – revised 2013 (<http://www.who.int/malaria/publications/atoz/9789241502092/en/>).
4. The percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or in a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density, the RDT must show a positive result in four tests (two RDTs per lot for two lots); at the higher

evaluated at both the lower and the higher parasite density. The thermal stability of the products⁵ and their ease of use are also evaluated.

Product resubmissions and anomalies observed during product testing

Since round 5, a requirement has been added for re-submission of products for re-evaluation within 5 years of their original testing. Products that are not re-tested within this time are removed from the summary documents of tested products; in 2013–2014, this concerned products tested in round 1 (2008). Also since round 5, anomalies observed during RDT product testing are recorded. The full results of rounds 1–5 of testing are available at http://www.who.int/entity/malaria/publications/atoz/9789241507554-summary_eng.pdf.

Product variation

As manufacturers may modify their product between rounds of WHO product testing and as the results of product testing may be applied only to a specifically defined, labelled, unique product, manufacturers are requested to inform the product testing programme of variations in products. In the case of prequalified products, manufacturers should review the WHO procedure for changes to a WHO prequalified in vitro diagnostic product and follow appropriate procedures (http://www.who.int/diagnostics_laboratory/evaluations/140627_changes_guidance_final.pdf).

For products that have not been prequalified, the WHO–FIND RDT Evaluation Programme Steering Committee takes a decision about the potential impact of the proposed design or constituent change on the stability and accuracy of the RDT. Annex 2 lists common product variations and the corresponding requirements for product assessment. Some modifications do not have to be notified to the WHO product testing programme; however, when the changes made might significantly affect the accuracy of the RDT,⁶ data on equivalence of performance will be required in order to demonstrate that the performance of the modified product is equivalent to that of the product previously submitted for testing. Data on equivalent performance can be generated in a specific assessment performed according to a WHO protocol at a designated, independent laboratory or by resubmission to the WHO product testing programme. The results of independent laboratory testing will be published in Annex 1 of an amended *WHO information note on recommended selection criteria for procurement of malaria rapid diagnostic tests*. Annex 3 lists notifications of product variation received in 2013, the recommended assessment and the results.

WHO selection criteria for procurement of RDTs

Experts convened at the inaugural meeting of the Malaria Policy Advisory Committee, held in Geneva in early 2012, updated the WHO recommendations for procurement of RDTs.⁷ Products should be selected according to the following criteria, after assessment in the malaria RDT product testing programme:⁸

- For the detection of *P. falciparum* in all transmission settings, the panel detection score against *P. falciparum* samples should be at least 75% at 200 parasites/μL.
- For the detection of *P. vivax* in all transmission settings, the panel detection score against *P. vivax* samples should be at least 75% at 200 parasites/μL.
- The false-positive rate should be less than 10%.
- The invalid rate⁹ should be less than 5%.

parasite density, it must show a positive result in two tests (one RDT per lot for two lots). Thus, the panel detection score is a combined measure of positivity rate, incorporating inter-test and inter-lot consistency. Consequently, it is not the same as the clinical sensitivity of an RDT, which is a measure of the proportion of people known to have the disease who test positive for it.

5. Assessed after 2 months of storage at temperatures of 35 °C and 45 °C and 75% humidity.
6. For example, changes in raw materials or components, including monoclonal antibodies, signal reagents, buffers and nitrocellulose membranes, or in cassette design
7. WHO Malaria Policy Advisory Committee and Secretariat. Inaugural meeting of the Malaria Policy Advisory Committee to the WHO: conclusions and recommendations. *Malar J* 2012;11:137 (<http://www.malariajournal.com/content/11/1/137>).
8. The full report of round 5 of the WHO malaria RDT product testing programme is available at http://apps.who.int/iris/bitstream/10665/128678/1/9789241507554_eng.pdf.
9. Proportion of tests deemed invalid, i.e. with no visible control band.

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

FIND maintains an interactive web-based guide designed to short-list RDTs according to programme needs and recommended selection criteria. The guide is based on the performance of the tests in rounds 2–5 of the product testing programme and can be found at: http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp.

The interactive guide allows selection of RDTs on the basis of: the target malaria species, the panel detection score for *P. falciparum* at 200 and 2000 parasites/ μ L, the panel detection score for *P. vivax* at 200 and 2000 parasites/ μ L, false-positive rate, invalid rate, test format and heat stability.

Additional considerations in procurement of malaria RDTs

Stability requirements at temperatures of intended storage, transport and use

RDTs submitted to WHO for testing are evaluated against a single cultured *P. falciparum* isolate at 200 parasites/ μ L at baseline and after 60 days of incubation at 35 °C and 45 °C. It is recommended that RDTs with high thermal stability be selected for use in areas with very high ambient temperatures.

Ease of use and training requirements for health workers

RDTs submitted to WHO for testing are also evaluated for blood safety, the quality of the instructions, the number of steps, the time to results, the blood transfer device, the format and kit completeness. Cassettes are easier to use than dipsticks. For reasons of blood safety, kits that include lancets and alcohol swabs are preferred to kits that do not contain these items. The report of round 5 of product testing of malaria RDTs gives guidance on assessing ease of use in the field.¹⁰

Price

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

Programme requirements¹¹

It is not the aim of this WHO information note to recommend that national health authorities immediately replace the malaria RDTs being used on a wide scale with new tests. The diagnostic performance of RDTs in the field depends on all the parameters listed above as well as on the effectiveness of training and supervision and the functioning of the supply management system. For programmes in which RDTs are used on a wide scale, continued use of the currently used tests may be appropriate until a decrease in malaria transmission indicates that alternative diagnostics with better performance are required to detect low-level parasitaemia. Plans to replace RDTs should be devised carefully, taking into consideration the training and supervision necessary to support the introduction of new RDTs and the production capacity and expected time for deliveries from the suppliers of the new RDTs.

For a comprehensive guide to procurement of malaria RDTs, beyond selection criteria, see the WHO manual on Good practices for selecting and procuring rapid diagnostic tests for malaria.¹² The manual contains practical advice on quantification, budgeting, technical specifications for tenders, management of tenders and contracts, supply management up to the arrival of goods at the port of entry, monitoring of supplier performance and managing product variations.

10. World Health Organization–FIND. *Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 5 (2013)*. Geneva; 2014 (http://apps.who.int/iris/bitstream/10665/128678/1/9789241507554_eng.pdf).

11. This section is based on advice from the WHO Global Malaria Programme secretariat and not on recommendations by experts convened for a WHO technical consultation.

12. World Health Organization. *Good practices for selecting and procuring rapid diagnostic tests for malaria*. Geneva; 2011 (http://whqlibdoc.who.int/publications/2011/9789241501125_eng.pdf).

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 before or after shipment, at a lot-testing centre that collaborates with the WHO–FIND malaria RDT product testing programme, as part of good procurement practice. Currently, this service is free of charge from two laboratories affiliated with WHO–FIND.¹³ Full information on WHO-recommended procedures for RDT lot testing are available at: http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/lot_testing/.

13. Research Institute for Tropical Medicine, Muntinlupa City, Philippines, and Institut Pasteur in Cambodia in Phnom Penh.

Annex 1. Performance of malaria RDTs in rounds 2–5 of WHO malaria RDT product testing

The table below is based on Table S2 in the summary results of rounds 1–5 of WHO product testing of malaria RDTs (http://www.who.int/entity/malaria/publications/atoz/9789241507554-summary_eng.pdf), with the tested products in alphabetical order by brand name, catalogue number and manufacturer. The WHO-recommended selection criteria for RDT procurement were applied to this list. With the results of rounds 2–5 of the RDT product testing programme as the basis, a green box indicates that the recommended criterion has been met, whereas a white box indicates that the criterion has not been met.

Disclaimer

Reference to any company or product in this information note does not constitute an endorsement, certification or warranty of fitness by WHO of the company or product for any purpose and does not imply any preference over companies or products of a similar nature that are not mentioned. Furthermore, WHO does not warrant that the lists are complete or error-free or that any products listed are of acceptable quality or 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 of the names of any products in this information note, particularly in any of the lists on pages 6–11, does not imply approval by WHO of these products (which is the sole prerogative of national authorities).

The results of the WHO malaria RDT product testing programme are used by the WHO programme of prequalification of diagnostics and medical devices as the laboratory evaluation component of prequalification of malaria RDTs. Although it is not currently a requirement for WHO procurement, manufacturers are encouraged to apply for WHO prequalification. A regularly updated list of WHO-prequalified diagnostics, including malaria RDTs, is available at http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en.

WHO recommendations for procurement of malaria RDTs are currently based on attainment of a set of minimum performance criteria. These recommendations were established by the WHO Malaria Policy Advisory Committee in 2012¹⁴ and are outlined in this report and presented in full in a WHO information note (http://www.who.int/malaria/publications/atoz/rdt_selection_criteria_en.pdf). Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO.

The lists of malaria RDTs included in this information note are not exhaustive. They include those products that were submitted for evaluation in rounds 2–5 of the WHO malaria RDT product testing programme and indicate the extent to which these products, as manufactured by the listed companies, were found at the time of their evaluation to meet the above-mentioned set of minimum performance criteria. The evaluation results indicated in the figures and tables apply only to the specific product listed with its unique product code or catalogue number, as manufactured by the listed company.

Improper storage, transport and handling of malaria RDTs may affect their performance.

Products that are not included in the lists in this information note have not or not yet been submitted for evaluation by the WHO malaria RDT product testing programme, or their evaluation has not yet been completed and published. It does not reflect the products' performance. The lists are updated regularly, and malaria RDTs are added as and when (after voluntary participation in the WHO malaria RDT product testing programme) they have been evaluated against the minimum performance criteria.

Although the malaria RDTs listed are regularly re-evaluated, and updated evaluation results are published by WHO, WHO cannot represent that products included in the lists will continue to meet the performance criteria in the same manner as indicated. WHO recommends, therefore, that before procuring a malaria RDT, each lot of that product be tested at one of the two following lot-testing laboratories: the Institut Pasteur of Cambodia or the Research Institute for Tropical Medicine, Philippines.

WHO disclaims any and all liability and 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 listed on pages 6–11 of this information note.

This information note may not be used by manufacturers or suppliers for commercial or promotional purposes.

14. WHO Malaria Policy Advisory Committee and Secretariat. Inaugural meeting of the malaria policy advisory committee to the WHO: conclusions and recommendations. *Malar J* 2012;11:137 (<http://www.malariajournal.com/content/11/1/137>).

Performance of malaria RDTs in rounds 2–5 of the WHO malaria RDT product testing programme

Performance criteria: A: *P. falciparum* panel detection score \geq 75% at 200 parasites/ μ L
 B: *P. vivax* panel detection score \geq 75% at 200 parasites/ μ L
 C: false-positive rate against clean negatives < 10%
 D: invalid rate < 5%

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
P.f. only							
ABON™ Malaria P.f. Rapid Test Device (whole blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	0.4	0	4
Advanced Quality™ One Step Malaria Pf Test ^a	ITP11002TC1/TC40	InTec Products, Inc.	53.0	NA	7.7 (233)	0.4	5
Advantage P.f. Malaria Card ^a	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	0.0	0.0	5
BIOCREDIT Malaria pf (HRP II)	HR0100	RapiGen Inc.	99.0	NA	99.1 (231)	0.5	4
BIONOTE Malaria P.f. Ag Rapid Test Kit	RG19-11	Bionote, Inc.	85.9	NA	2.0	0.1	3
CareStart™ Malaria HRP2 (Pf) ^a	G0141	Access Bio, Inc.	91.0	NA	0.9	0.0	5
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	NA	3.0	0.0	2
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	1.0 (198)	0.3	3
Diagnosticks Malaria (Pf) Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	88.0	NA	0.9 (235)	0.3	5
Diagnosticks Malaria (Pf) Dipstick WB	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	NA	2.0	0.0	2
First Response® Malaria Ag <i>P. falciparum</i> (HRP2) card test ^a	I13FRC	Premier Medical Corporation Ltd	95.0	NA	0.4	0.0	5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	2.2 (231)	0.2	4
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd	87.0	NA	1.0	0.1	2
ICT Diagnostics Malaria P.f. ^a	ML01	ICT International	86.9	NA	0.0	0.0	3
Immunoquick Contact falciparum	0519K25	Biosynex	81.8	NA	4.0 (199)	0.3	3
Immunoquick® Malaria falciparum ^a	0502_K25	Biosynex	72.0	NA	5.1 (234)	0.2	5
IND One-Step Malaria Antigen P.f	535-11	IND Diagnostics Inc.	61.2	NA	6	0.1	4
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd	79.0	NA	10.6 (235)	0.7	5
Maleriscan® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	0.4	0.2	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	0.0	0.3	3

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
One Step Malaria P.F Test (Cassette) ^a	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd	94.9	NA	1.3	0	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	NA	11.0	0.0	2
OnSite Pf Ag Rapid Test ^a	R0114C	CTK Biotech, Inc.	85.9	NA	3.5	0.0	3
Paracheck® Pf-Rapid Test for P. falciparum Malaria Device (Ver.3) ^a	302030025	Orchid Biomedical Systems	95.9	NA	1.3	0	4
Paracheck® Pf-Rapid Test for P. falciparum Malaria Dipstick (Ver.3) ^a	302040025	Orchid Biomedical Systems	70.4	NA	0.9	0	4
ParaHIT® -f (Device)	55IC104-50	Span Diagnostics Ltd	84.9	NA	0.0	0.0	3
ParaHIT® -f (Dipstick)	55IC103-50	Span Diagnostics Ltd	80.8	NA	2.5	0.0	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) ^h	05FK90	Standard Diagnostics Inc.	87.9	NA	2.0	0.0	3
SD BIOLINE Malaria Ag Pf ^a	05FK50/05FK53	Standard Diagnostics, Inc.	95.0	NA	0.0	0.0	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	88.8	NA	5.2 (230)	0.7	4
Vision Malaria Pf ^a	VB01	Vision Biotech (Pty) Ltd	84.0	NA	5.1 (235)	0.1	5
Wondfo One Step Malaria P.f Test ^a	W 37-C	Guangzhou Wondfo Biotech Co. Ltd	89.8	NA	0.4 (231)	0.2	4
P.f. and pan							
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd	69.7	0.0	0.0	0.0	3
ABON™ Plus Malaria P.f/Pan Rapid Test Device (whole blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	0.4	0.0	4
ACCUCARE One-Step Malaria Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) Pvt. Ltd	66.0	37.1	7.3 (234)	0.4	5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	8.7 (231)	2.1	5
Advantage Mal Card ^a	IR221025	J. Mitra & Co. Pvt. Ltd	30.0	94.3	0.4	0.0	5
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd	84.0	100.0	0.0	0.2	5
AZOG Malaria pf (HRPII)/pf (LDH)/ (pan-LDH) Antigen Detection Device ^b	MFV-124F	AZOG, Inc.	62.2	0.0	1.7 (231)	0.3	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	77.0	77.1	4.7	0.2	5
BIONOTE Malaria P.f. & Pan Ag Rapid Test Kit	RG19-08	Bionote, Inc.	93.9	88.6	3.0 (199)	0.1	3
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	77.0	77.1	0.4	0.0	5
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	0.0	0.2	3

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
CareStart™ Malaria HRP2/pLDH (Pf/Pan) COMBO ^a	G0131	Access Bio, Inc.	90.0	94.3	0.4	0.0	5
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	0.5	0.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	2.5 (199)	0.1	3
Clearview® Malaria Combo ^a	VB11	Vision Biotech (Pty) Ltd	82.8	5.7	3.5	0.0	3
Clearview® Malaria Dual ^a	VB20	Orgenics Ltd.(IS)	89.0	60.0	12.7	0.0	5
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	32.2 (230)	0.3	4
Diagnosticks Malaria (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	98.0	51.4	2.5	0.3	3
DIAQUICK Malaria P.f/Pan Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	2.1	0.2	5
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit ^a	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd)	83.0	80.0	1.3 (235)	0.3	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test ^a	I16FRC	Premier Medical Corporation Ltd	85.0	74.3	0.0	0.0	5
FirstSign™ ParaView (Pan+Pf) ^a	2101CB-25	Unimed International Inc.	87.8	61.8	2.6	0.0	4
GenBody™ Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	0 (235)	0.2	5
Genedia® Malaria P.f/Pan Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Republic of Korea)	67.0	17.1	10.6	0.1	5
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd	20.0	15.0	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd	84.0	75.0	0.5	0.0	2
Humasis Malaria P.f/Pan Antigen Test ^a	AMAL-7025	Humasis, Co., Ltd	90.0	91.4	0.9 (235)	0.7	5
ICT Malaria Dual Test ^a	ML03	ICT International	93.0	40.0	3.0	0.0	5
ICT Malaria Combo ^a	ML02	ICT International	76.5	5.9	0.4	0.1	4
Immunoquick Contact Malaria +4	0525K25	Biosynex	75.8	17.1	2.0	0.3	3
IND One-step Malaria Antiegn P.f/Pan Test	535-10	IND Diagnostics Inc.	94.9	61.8	1.3	0.0	4
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	54.6	0.0	44.0	0.0	3
Malaria Pf./Pan Antigen Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	0.9	0.2	5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device ^a	MFV-124R	AZOG, Inc.	95.0	0.0	5.5 (199)	0.3	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	63.3	2.9	0.0	0.1	4
Malaria pf (pLDH) / Pan-pLDH Test Device ^a	MFV-124	AZOG, Inc.	41.0	8.6	81.3 (235)	0.1	5
Malaria Pf/ Pan	GM004	Genomix Molecular Diagnostics	39.8	2.9	0.0	0.0	4

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
		Pvt. Ltd					
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd	89.0	91.4	0.4 (232)	1.0	5
Malascan™ Device - Rapid test for Malaria Pf/Pan ^a	50402025	Zephyr Biomedical Systems	82.8	57.1	1.0 (195)	1.9	3
MD Malaria Pf/Pan (pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	95.0	28.6	39.4	0.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	0.9	0.1	4
NanoSign Malaria pf/pan Ag 3.0 ^a	RMAP10	Bioland Ltd	92.9	97.1	0.4	0.0	4
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd	6.1	8.6	0.0	0.1	3
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	15.3	0.1	5
One Step Malaria P.f./Pan Test ^a	W56-C	Guangzhou Wondfo Biotech Co. Ltd	37.4	85.7	4.1 (195)	2.4	3
OnSite Pf/Pan Ag Rapid Test ^a	R0113C	CTK Biotech, Inc.	86.0	88.6	1.3	0.1	5
OptiMAL-IT	710024	Diamed, a division of Bio-Rad	50.5	97.1	2.0 (198)	0.5	3
ParaHIT - Total Ver. 1.0 (device)	55IC204-10	Span Diagnostics Ltd	84.7	82.4	0.0	0.1	4
ParaHIT - Total Ver. 1.0 (dipstick)	55IC203-10	Span Diagnostics Ltd	76.5	61.8	0.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	64.0	10.0	7.0	0.0	2
Parascreen® Rapid test for Malaria Pan/Pf ^a	50310025	Zephyr Biomedicals	92.0	37.1	4.2	0.1	5
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd	74.0	40.0	14.0	0.0	5
SD BIOLINE Malaria Ag P.f./Pan ^a	05FK60/05FK63	Standard Diagnostics Inc.	94.0	91.4	0.0	0.0	5
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	90.8	94.1	1.3 (226)	2.8	4
SD BIOLINE Malaria Ag ^a	05FK40	Standard Diagnostics Inc.	16.2	97.1	0.0	0.0	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd	83.8	0.0	1.0	0.0	3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	1.3 (235)	0.3	5
Pf and Pv/Pvom							
Advanced Quality™ One Step Malaria P.f./P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	86.9	0.0	18.5	0.2	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd	77.8	31.4	0.0	0.0	3
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	81.0	34.3	0.4 (235)	0.2	5
BIONOTE Malaria P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote, Inc.	92.9	97.1	4.0	0.0	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) Combo ^a	G0161	Access Bio, Inc.	90.8	94.1	0.0	0.0	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) Combo ^a	G0171	Access Bio, Inc.	89.8	91.2	0.0	0.0	4

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	98.0	60.0	4.0	0.1	3
Diagnosticks, Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	91.0	45.0	2.0	0.1	2
FalciVax™ - Rapid test for Malaria Pv/Pf ^a	50300025	Zephyr Biomedicals	98.0	88.2	7.3	0.0	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	0.4	0.1	4
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	0.0	0.0	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	1.3	0.0	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	0.0 (230)	0.5	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	79.8	0.0	0.0 (199)	0.1	3
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	0.9 (232)	2.5	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.8	0.0	0.9	0.0	4
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test ^a	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	3.0 (232)	0.7	5
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	52.0	0.0	1.5 (199)	0.4	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	90.8	94.1	0.0	0.0	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	89.8	91.2	0.0	0.0	4
One Step Malaria P.F/P.V Test (Cassette) ^a	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	77.1	0.0	5
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	92.0	37.5	3.5	0.1	2
OnSite Pf/Pv Ag Rapid Test ^a	R0112C	CTK Biotech, Inc.	79.6	100.0	1.3	0.0	4
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device	551C402-50	Span Diagnostics Ltd.	63.0	37.1	6.4	0.1	5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	4.3	0.0	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv ^b	05FK100	Standard Diagnostics Inc.	96.9	97.1	2.2	0.0	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80/05FK83	Standard Diagnostics, Inc.	96.0	95.0	3.5	0.2	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	32.0 (231)	0.5	4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	87.0	28.6	2.1	0.1	5

Product	Catalogue number*	Manufacturer	Performance criteria				Round
			A	B	C	D	
Pf, Pv and pan							
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	92.9	11.4	3.5 (198)	1.0	3
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	93.9	11.4	4.0 (199)	1.1	3
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	89.0	45.0	24.5	0.1	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	93.0	45.0	37.0 (198)	0.7	2
Pan only							
Advantage Pan Malaria Card ^a	IR013025	J. Mitra & Co. Pvt. Ltd.]	77.0	100.0	0.4	0.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0	2.2	0.2	4
CareStart™ Malaria pLDH (Pan) ^a	G0111	Access Bio, Inc.	84.0	88.6	0.0	0.0	5
Clearview® Malaria pLDH ^a	70884025	Orgenics Ltd. (Inverness Medical Innovations)	81.8	85.7	13.5	0.5	3
Diagnosticks Malaria (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	0.0	0.3	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corp. Ltd.	31.0	92.5	0.0	0.0	2
FirstSign™ PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	25.0	82.5	2.5	0.2	2
OnSight™ PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	22.0	77.5	2.5	0.2	2
Parabank™ Device, Rapid test for Malaria Pan ^a	50301025	Zephyr Biomedical Systems	17.2	62.9	0.5	0.2	3
Pv only							
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	92.5	1.0	0.0	2

* Some production may have different catalogue numbers for different box sizes or kit accessories; contact manufacturers for detailed information.

Pan: All *Plasmodium* species; Pf: *Plasmodium falciparum*; Pv: *Plasmodium vivax*; Pvom: *Plasmodium vivax, ovale* and *malariae*

^a Product resubmission, results from most recent round of testing replace previous results. Refer to summary results of WHO product testing of malaria RDTs: rounds 1–5 (2008–2013), Table S3.

^b Panel detection score in the table is based on a positive Pf test line (either Pf-HRP2 or Pf-pLDH). For test line-specific results, refer to the tables and annexes in the full reports.

Annex 2. Changes in malaria RDT manufacture and corresponding required product performance assessment

Area of modification	Product variation	Resubmit to WHO product testing as new product	Requires equivalence testing at independent laboratory	No notification required
Test kit				
Format	Type (e.g. cassette, dipstick)	✓		
	Length or size		✓	
	Number of wells	✓		
	Well placement		✓	
Monoclonal antibody	Target	✓		
	Source (clone)	✓		
	Source (manufacturer)			✓
Dye conjugate	Type (material)	✓		
	Source			✓
	Size			✓
Nitrocellulose	Composition	✓		
	New manufacturer			✓
Buffer	Change in constituents			✓
	Change in concentrations			✓
Blood transfer device	Type			✓
Process				
Timing	Steps		✓	
	Reading		✓	
Volumes	Blood		✓	
	Buffer			✓

Annex 3. Notifications of product variations to the WHO malaria RDT product testing programme in 2013 (round 5): required assessment and outcome

Product(s)	Catalogue number(s)	Manufacturer	Proposed modification	Required assessment	Outcome
CareStart™ Malaria HRP2/pLDH (Pf/Pan) Combo	G0131	Access Bio, Inc.	Reduction in length of cassette from 70 mm to 60 mm	Demonstration of equivalence	Product equivalence in parasite detection rates
CareStart™ Malaria HRP2 (Pf)	G0141				
CareStart™ Malaria HRP2/pLDH (Pf/Pv) Combo	G0161				
CareStart™ Malaria HRP2/pLDH Pf test	G0181				