Recommended selection criteria for procurement of malaria rapid diagnostic tests

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INFORMATION NOTE

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[1] 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 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

World Health Organization

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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, 251 products have been evaluated in six rounds of product testing, comprising 171 unique products and 58 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 evaluated at both the lower and the higher parasite density. The thermal stability of the products[5] and their ease of use are also evaluated.

Product testing results are specific to a product and not to the manufacturing site; however, participating manufacturers are required to provide valid ISO13485 certificates for all manufacturing sites. ISO certificate details and authenticity will be verified with the certificate accreditation company.

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 2014–2015, this concerned products tested in round 2 (2009). Since round 5, anomalies observed during RDT product testing were recorded, and in round 6 frequency of anomalies was also documented. The full results of rounds 1–6 of testing are available at http://www.who.int/malaria/publications/atoz/9789241510035/en/.

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/141203_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 since 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 rate[9] should be less than 5%.

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 3–6 of the product testing programme and can be found at: http://www.finddiagnostics.org/programs/malaria-afs/malaria/current-projects/rdt_quality_control/interactiveguide-intro/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/µL, the panel detection score for *P. vivax* at 200 and 2000 parasites/µL, false-positive rate, invalid rate, test format, heat stability and procedural characteristics to enable rapid selection of products with the same: blood volume requirement, number of buffer drops and time until result.

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/µL at baseline and after 60 days of incubation at room temperature, 35 °C and 45 °C. For the first time in round 6, heat stability of pan and *P. vivax* detecting products was assessed against a wild-type *P. vivax* sample. It is recommended that RDTs with high thermal stability be selected for use in areas with very high ambient temperatures.

Ease of use, anomalies 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 6 of product testing of malaria RDTs gives guidance on assessing ease of use in the field.[10] Occasionally unexpected

features, referred to as anomalies appear while performing RDTs; these include red background, incomplete clearing, ghost lines and patchy lines among others. Anomalies may be attributed to defects in the manufacturing process, damage that has occurred to the RDTs during storage, or as a consequence of end user error. While anomalies have been documented internally since round 1, the frequency of anomalies was captured for the first time in round 6. Since anomalies may interfere with correct interpretation of results, manufacturers are encouraged to reduce or eliminate anomalies where possible, and end-users should be aware of those that occur commonly and the appropriate action to take in response.

Price

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

Programme requirements[11]

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. Categorization of products according to the same procedural characteristics was included in the round 6 report and the interactive online guide to help end users identify products with the same protocol; if similar products are used in the case of RDT stock outs, this may help reduce end user error, and the need for retraining.

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.

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.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/evaluation-lot-testing/en/ and for compiled results of lots evaluated go to: http://www.finddiagnostics.org/about/what_we_do/successes/malaria_rdt_lot_testing_results/index.html.

RDT single packs and single use buffer vials

During 2014-2015, ten RDT single-pack products from 3 manufacturers, exhibited evaporation from single use buffer vials at the time of interval testing (after approximately 18 months of incubation at 37 °C and ~20% humidity). In 57 lots,

there was insufficient buffer left to do testing and also concerns the unknown effect concentrated buffer reagents could have on have upon test accuracy. Subsequent field reports of buffer evaporation from single use vials have emerged from various countries. To this end, WHO has issued an information note (http://www.who.int/diagnostics_laboratory/procurement/151009_single_buffer_ampulla_information_notice_for_users_v5.pdf) recommending that RDTs with multiuse buffer bottles be used until manufacturers have demonstrated stability of the single use buffer vials over the product shelf-life and in tropical conditions.

In March 2016, WHO prequalification of in vitro diagnostics relisted two products containing modified single-use buffer vials based on satisfactory demonstration of stability. These product codes are now included in Annex 1, more specifically, they are SD BIOLINE Malaria Ag Pf (05FK53) and SD BIOLINE Malaria Ag P.f/Pan (05FK63). Review is ongoing for other products and information notes will be updated in accordance with the findings.

Notes

1. This information note on recommended selection criteria for procurement of malaria rapid diagnostic tests replaces earlier versions released between 2009 and 2014.
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 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 room temperature, or 35 °C or 45 °C with 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 6 of the WHO malaria RDT product testing programme is available at http://www.who.int/malaria/publications/atoz/9789241510035/en/
9. Proportion of tests deemed invalid, i.e. with no visible control band.
10. World Health Organization–FIND. Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTS: round 6 (2014-2015). Geneva; 2015 (http://www.who.int/malaria/publications/atoz/9789241510035/en/).
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).
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 3–6 OF WHO MALARIA RDT PRODUCT TESTING

The table below is based on Table S2 in the summary results of rounds 1–6 of WHO product testing of malaria RDTs (http://apps.who.int/iris/bitstream/10665/204119/1/9789241510042_eng.pdf , with the tested products in alphabetical order by product name, catalogue number and manufacturer. The WHO-recommended selection criteria for RDT procurement were applied to this list. With the results of rounds 3–6 of the RDT product testing programme as the basis, a blue box indicates that the recommended criterion has been met, whereas a white box indicates that the criterion has not been met., the final column indicates if all WHO procurement criteria have been met, and if the product has been WHO prequalified. For products to remain in the summary tables, manufacturers must confirm continued product availability and must comply with compulsory resubmission rules. If these requirements are not met, products will be delisted and will not be eligible for procurement.

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 7–16, 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, the WHO Global Malaria Programme is assessing the impact of making WHO prequalification a requirement. This would include dossier and manufacture site assessment in addition to the laboratory evaluation. Manufacturers are therefore encouraged to apply to 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 2012[1] 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 3–6 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 7–16 of this information note.

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

Note

1. 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 3–6 of the WHO malaria RDT product testing programme

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

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
PF ONLY								
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd.	32.7	NA	0.4	0	4	No
Advanced Quality™ One Step Malaria Pf Test[a]	ITP11002TC1/TC40	InTec Products, Inc.	53.0	NA	7.7 (233)	0.4	5	No
Advantage P.f. Malaria Card[a]	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	0.0	0.0	5	Yes
BIONOTE MALARIA P.f. Ag Rapid Test Kit[a]	RG19-11	Bionote,Inc.	88.0	NA	0.5	0.0	6	Yes
CareStart™ Malaria HRP2 (Pf)[a]	RMOM(U)-XXX7X/ RMOM(U)-XXX9X [b,c]	Access Bio, Inc.	91.0	NA	0.9	0.0	5	Yes[d]
CareStart™ Malaria HRP2/pLDH Pf test	RMPM(U)-XXX7X/ RMPM(U)-XXX9X [b,e]	Access Bio, Inc.	91.0	NA	0.0	0.0	6	Yes[d]
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	1.0 (198)	0.3	3	Yes
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	71.0	NA	1.0	0.1	6	No
First Response® Malaria Ag P. falciparum (HRP2) Card Test[a]	I13FRC25	Premier Medical Corporation Ltd.	95.0	NA	0.4	0.0	5	Yes[d]
First Response® Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	1.0	0.0	6	Yes
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	2.2 (231)	0.2	4	Yes
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	1.4	0.0	6	Yes
ICT Diagnostics Malaria P.f.[a]	ML01	ICT INTERNATIONAL	86.9	NA	0.0	0.0	3	Yes
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	NA	4.0 (199)	0.3	3	Yes
IMMUNOQUICK® MALARIA falciparum[a]	0502_K25	Biosynex	72.0	NA	5.1 (234)	0.2	5	No
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	No
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	91.0	NA	1.0	0.0	6	Yes
Maleriscan® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (P) Ltd.	83.7	NA	0.4	0.2	4	Yes
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd.	84.9	NA	0.0	0.3	3	Yes

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
One Step Malaria P.f Whole blood Test[a]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	NA	0.0	0.0	6	Yes
One Step Malaria P.F Test (Cassette)[a]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	1.3	0	4	Yes
OnSite Malaria Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	75.0	NA	0.0	0.2	6	Yes
Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver.3)[a]	302030025	Orchid Biomedical Systems	95.9	NA	1.3	0	4	Yes
Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)[a]	302040025	Orchid Biomedical Systems	70.4	NA	0.9	0	4	No
ParaHIT® - f Ver. 1 (Device)	55IC104-50	ARKRAY Healthcare Pvt. Ltd. [f]	84.9	NA	0.0	0.0	3	Yes[d]
ParaHIT® - f Ver. 1 (Dipstick)	55IC103-50	ARKRAY Healthcare Pvt. Ltd. [f]	80.8	NA	2.5	0.0	3	Yes[d]
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	0.0	0.2	6	Yes
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	0.5 (207)	0.2	6	Yes
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	0.0	0.0	6	Yes
SD Bioline Malaria Ag P.f (HRP2/pLDH)[a,g]	05FK90	Standard Diagnostics, Inc.	88 (87.0/52.0)[k]	NA	0.0	0.0	6	Yes[d]
SD BIOLINE Malaria Ag Pf[a]	05FK50/05FK53	Standard Diagnostics, Inc.	95.0	NA	0.0	0.0	5	Yes[d]
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	88.8	NA	5.2 (230)	0.7	4	Yes
PF AND PAN								
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	No
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	No
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	8.7 (231)	2.1	5	No
Advantage Mal Card[a]	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	0.4	0.0	5	No
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	0.0	0.2	5	Yes
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	90.0	22.9	0 (207)	0.2	6	No
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[g]	MFV-124F	AZOG, INC.	62.2/3.1[k]	0.0	1.7 (231)	0.3	4	No
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit[a]	RG19-08	Bionote, Inc.	83.0	68.6	0.5	0.0	6	No
BioTracer™ Malaria P.f/PAN Rapid Card[a]	17012	Bio Focus Co., Ltd.	83.0	100.0	0.0	0.0	6	Yes

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	0.0	0.2	3	Yes
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO[a]	RMRM(U)-XXX7X/ RMRM(U)-XXX9X [b,h]	Access Bio, Inc.	90.0	94.3	0.4	0.0	5	Yes[d]
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	0.5	0.0	3	Yes
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	2.5 (199)	0.1	3	Yes
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics	99.0	26.5	32.2 (230)	0.3	4	No
Diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	98.0	51.4	2.5	0.3	3	No
DIAQUICK Malaria P.f/Pan Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	2.1	0.2	5	Yes
EzDx™ Malaria Pan/Pf Rapid test detection Kit[a]	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	1.4	0.0	6	Yes
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[a]	I16FRC	Premier Medical Corporation Ltd.	85.0	74.3	0.0	0.0	5	No
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	1.9 (207)	0.1	6	Yes
FirstSign™ ParaView (Pan+Pf)[a]	2101CB-25	Unimed International Inc.	87.8	61.8	2.6	0.0	4	No
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	0 (235)	0.2	5	No
Genedia® Malaria P.f/Pan Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	10.6	0.1	5	No
Humasis Malaria P.f/Pan Antigen Test[a]	AMAL-7025	Humasis, Co., Ltd.	90.0	91.4	0.9 (235)	0.7	5	Yes
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	89.0	62.9	0.5	0.1	6	No
ICT Malaria Dual Test[a]	ML03	ICT INTERNATIONAL	93.0	40.0	3.0	0.0	5	No
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	2.0	0.3	3	No
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	88.0	91.4	1.0 (206)	0.8	6	Yes
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	54.6	0.0	44.0	0.0	3	No
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	0.9	0.2	5	No
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	No
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	No
Malaria pf (pLDH) / PAN-pLDH Test Device[a]	MFV-124	AZOG, INC.	41.0	8.6	81.3 (235)	0.1	5	No

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt. Ltd.	39.8	2.9	0.0	0.0	4	No
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	Yes
Malascan™ Device - Rapid test for Malaria Pf/Pan[a]	50402025	Zephyr Biomedicals	82.8	57.1	1.0 (195)	1.9	3	No
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	0.9	0.1	4	No
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	77.0	71.4	0.5	0.0	6	No
NanoSign Malaria pf/pan Ag 3.0[a]	RMAP10	Bioland, Ltd.	92.9	97.1	0.4	0.0	4	Yes
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd.	6.1	8.6	0.0	0.1	3	No
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	15.3	0.1	5	No
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	No
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	77.0	14.3	0.0	0.0	6	No
OnSite Malaria Pf/Pan Ag Rapid Test[a]	R0113C	CTK Biotech, Inc.	78.0	85.7	0.0 (207)	0.2	6	Yes
OptiMAL-IT[a]	710024	Diamed - A Division of Bio-Rad	50.5	97.1	2.0 (198)	0.5	3	No
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	ARKRAY Healthcare Pvt. Ltd. [f]	84.7	82.4	0.0	0.1	4	Yes
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	ARKRAY Healthcare Pvt. Ltd. [f]	76.5	61.8	0.0	0.0	4	No
Parascreen® - Rapid Test for Malaria Pan/Pf[a]	503030025	Zephyr Biomedicals	79.0	97.1	0.0	0.0	6	Yes
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	7.2	0.1	6	Yes
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)[a]	C30RHA25	RapiGEN Inc.	90.0	91.4	2.4 (207)	0.1	6	Yes
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co., Ltd.	74.0	40.0	14.0	0.0	5	No
SD BIOLINE Malaria Ag P.f/Pan[a]	05FK60/05FK63	Standard Diagnostics, Inc.	94.0	91.4	0.0	0.0	5	Yes[d]
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics, Inc.	90.8	94.1	1.3 (226)	2.8	4	Yes
SD BIOLINE Malaria Ag[a]	05FK40	Standard Diagnostics, Inc.	16.2	97.1	0.0	0.0	3	No
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	1.3 (235)	0.3	5	No

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
PF AND PV/PVOM								
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)[a]	ITP11003 TC40	InTec Products, Inc.	74.0	48.6	0 (207)	0.7	6	No
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	77.8	31.4	0.0	0.0	3	No
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	81.0	34.3	0.4 (235)	0.2	5	No
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	92.9	97.1	4.0	0.0	3	Yes
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	0.0	0.1	6	Yes
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[a]	RMVM(U)-XXX7X/ RMVM(U)-XXX9X [b,i]	Access Bio, Inc.	90.8	94.1	0.0	0.0	4	Yes[d]
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[a]	G0171/G0171-ET	Access Bio, Inc.	89.8	91.2	0.0	0.0	4	Yes
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	98.0	60.0	4.0	0.1	3	No
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	78.0	82.9	0.0 (207)	0.5	6	Yes
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	3.9	0.0	6	Yes
FalciVax™ - Rapid Test for Malaria Pv/Pf[a]	503010025	Zephyr Biomedicals	80.0	100.0	1.4	0.0	6	Yes
First Response® Malaria Ag *Pf/Pv* Card Test	PI19FRC	Premier Medical Corporation Ltd.	85.0	71.4	0.5 (207)	0.2	6	No
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	0.4	0.1	4	Yes
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	0.0	0.0	4	Yes
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	1.3	0.0	4	Yes
Humasis Malaria P.f/P.v Antigen Test [j]	ANMIV-7025	Humasis Co., Ltd.	88.0	91.4	1.0 (207)	0.1	6	Yes
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	91.0	48.6	0.0	0.0	6	No
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	No
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, INC.	79.8	0.0	0.0 (199)	0.1	3	No
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	No
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt. Ltd.	40.8	0.0	0.9	0.0	4	No
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	90.0	51.4	0.0 (203)	1.3	6	No

PRODUCT	CATALOGUE NUMBER*	MANUFACTURER	PERFORMANCE CRITERIA				ROUND	MEETS WHO PROCUREMENT CRITERIA
			A	B	C	D		
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	No
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	76.0	25.7	1.0	0.0	6	No
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	No
One Step Malaria P.f/P.v Whole Blood Test[a]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	78.0	0.0	0.0	0.1	6	No
OnSite Malaria Pf/Pv Ag Rapid Test[a]	R0112C	CTK Biotech, Inc.	74.0	80.0	0.0 (207)	0.2	6	No
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device	55IC402-50	ARKRAY Healthcare Pvt. Ltd.[f]	63.0	37.1	6.4	0.1	5	No
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	78.0	25.7	0.0	0.1	6	No
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems	92.9	79.4	4.3	0.0	4	Yes
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	4.4 (207)	0.2	6	Yes
SD Bioline Malaria Ag P.f/P.v[a]	05FK80	Standard Diagnostics, Inc.	92.0	94.3	1.9	0.0	6	Yes[d]
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	32.0 (231)	0.5	4	No
PF, PF AND PV								
SD Bioline Malaria Ag P.f/P.f/P.v[g]	05FK120	Standard Diagnostics, Inc.	85 (84.0/36.0 [l])	91.4	0.0	0.0	6	Yes
PF, PV AND PAN								
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	92.9	11.4	3.5 (198)	1.0	3	No
Diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	93.9	11.4	4.0 (199)	1.1	3	No
PAN ONLY								
Advantage Pan Malaria Card[a]	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	0.4	0.0	5	Yes
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0	2.2	0.2	4	No
CareStart™ Malaria pLDH (PAN)[a]	RMNM(U)-XXX7X[b,j]	Access Bio, Inc.	84.0	88.6	0.0	0.0	5	Yes[d]
Diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	0.0	0.3	3	No
Parabank™ Device - Rapid test for Malaria Pan[a]	50301025	Zephyr Biomedicals	17.2	62.9	0.5	0.2	3	No

Notes

* Some products may have different catalogue numbers for different box sizes or kit accessories or site of manufacture; 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 1–6 (2008–2015), Table S1.

b Please note, the first three letters in the catalogue number indicate the RDT product code, the 4th letter indicates the package type of the kit (M: multi kit, U: single kit). The XXX in the second part of the catalogue number indicates the number of RDTs in the kit, the number following this indicates the manufacturing site (e.g. 7:USA, 9: Ethiopia) and the last number indicates the CE marking (e.g. 1: CE marked, 2: Not CE marked).

c Catalogue number was formerly G0141/G0141-ET.

d WHO-prequalified product –public reports found here: http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

e Catalogue number was formerly G0181/G0181-ET.

Span Diagnostics Ltd. is now ARKRAY Healthcare Pvt.Ltd.

g 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.

h Catalogue number was formerly G0131/ G0131-ET.

i Catalogue number was formerly G0161/G0161-ET.

j Catalogue number was formerly G0111.

k Product PDS shown along with PDS for HRP2 band and Pf-pLDH band, respectively.

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	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 SINCE 2013: REQUIRED ASSESSMENT AND OUTCOME

PRODUCT(S)	CATALOGUE NUMBER(S)	MANUFACTURER	PROPOSED MODIFICATION	REQUIRED ASSESSMENT	OUTCOME
CareStart™ Malaria HRP2/pLDH (Pf/Pan) Combo	RMRM(U)-XXX7X/ RMRM(U)-XXX9X (formerly G0131/G0131-ET)	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)	RMOM(U)-XXX7X/ RMOM(U)-XXX9X (formerly G0141/G0141-ET)				
CareStart™ Malaria HRP2/pLDH (Pf/Pv) Combo	RMVM(U)-XXX7X/ RMVM(U)-XXX9X (formerly G0161/G0161-ET)				
CareStart™ Malaria HRP2/pLDH Pf test	RMPM(U)-XXX7X/ RMPM(U)-XXX9X (formerly G0181/G0181-ET)				