



Recommended selection criteria for procurement of malaria rapid diagnostic tests

EFFECTIVE DECEMBER 2018

INFORMATION NOTE

The aims of this WHO information note¹ are to list the criteria recommended for selecting tests, to provide a list of products meeting those criteria as well as 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

PRODUCT EVALUATIONS

The heterogeneous diagnostic performance of malaria RDTs currently available on the market can undermine the confidence of health professionals in the accuracy of these tests. Over the past decade, 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, has provided comparative data on the performance of the RDTs available on the market to guide procurement. Since 2008, 327 products have been fully evaluated in eight rounds of product testing, comprising 227 unique products and 61 product resubmissions. Each round

of product testing has begun 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 low- and high- parasite density including 20 culture-derived of *P. falciparum* samples, 100 of patient-derived *P. falciparum* samples, about 35 *P. vivax* parasite samples and a panel of 100 parasite-negative cultures. In round 8, a panel of 40 culture and patient-derived *pfhrp2/3* negative *P. falciparum* samples was included. This included both single (*pfhrp2*-/*pfhrp3*+) and double-deleted (*pfhrp2*-/*pfhrp3*-) parasites.

The main measure of performance against the parasite containing panels described above, 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 and their ease of use are also evaluated.⁵

Round 8 (<https://www.who.int/malaria/publications/atoz/9789241514965/en/>) is the last distinct 'round' of product evaluations coordinated by WHO/GMP and FIND. Product evaluations will now be performed continuously or in small batches, under the coordination of the WHO Prequalification of in vitro diagnostics (IVD) programme. All inquiries concerning product evaluations should be directed to: diagnostics@who.int and for details of the prequalification process: https://www.who.int/diagnostics_laboratory/evaluations/en/.

Product resubmissions and anomalies

Since round 5, there has been a requirement 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 found here: <https://www.who.int/malaria/publications/atoz/9789241514965/en/>. However, henceforth, there will be no requirement for product resubmission and monitoring will be via WHO prequalification of IVD procedures.

Since round 5, anomalies observed during RDT product testing were recorded.

Instructions for use and product labelling

In round 7 of WHO malaria RDT product testing, for the first time, adherence to a list of recommendations on instructions for use and product labelling was assessed. Overall, products scored well in this assessment for labelling of the main device and labelling of the device packaging and of the primary product box, with some exceptions, especially in warnings and precautions. The scores for adherence to recommendations on labelling of buffer bottles and other accessories were lower. The instructions for use were highly variable, with some important omissions, particularly on laboratory safety, product performance and interpretation.

It is expected with the availability of guidance⁶ that compliance will improve over time, and this will be monitored through the WHO Prequalification process.

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 have been requested to inform the product testing programme of variations in products.

Since round 8 and henceforth, a submission to the WHO Prequalification of in vitro diagnostic (IVD) programme is a prerequisite for product evaluation and therefore all manufacturers should now follow WHO PQ procedures to report changes to a product (http://www.who.int/diagnostics_laboratory/evaluations/141203_changes_guidance_final.pdf). Notification of changes to WHO prequalified products will be described in product specific public reports: http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/.

WHO SELECTION CRITERIA FOR PROCUREMENT OF RDTs AND CHANGES IN 2019

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/ μ L.
- 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/ μ L.
- The false-positive rate⁹ should be less than 10%.
- The invalid rate should be less than 5%.

In December 2017, the WHO prequalification of IVD programme and the Global Malaria Programme announced that all malaria rapid diagnostic tests that diagnose *P. falciparum*–only through detection of histidine rich protein 2 (HRP2) will be required to be prequalified for WHO procurement starting 1 January 2018.

The requirement for prequalification will be extended to include all HRP2, pan-LDH and/or pv-LDH combination RDTs as of January 2019.

Both the WHO prequalification of IVD programme and the Global Malaria Programme are closely monitoring the pipeline to ensure this plan is compatible with malaria endemic country needs and that it will not endanger supply security.

The WHO prequalification of IVDs programme will continue to accept new applications for all types of antigen-detecting malaria RDTs.

RDT procurers and national malaria control programmes are encouraged to review their policies for future malaria RDT procurements and to align them with these revised recommendations. Use of current malaria RDT stocks and existing contractual agreements need not be interrupted to meet these new requirements.

RDTs for areas with high prevalence of *pfhrp2/3* gene deletions

Due to the lack or limited number of WHO prequalified RDTs that can be used in areas with a high prevalence of *pfhrp2/3* deletions, the requirements for WHO procurement of pan-LDH-only RDTs and combination RDTs containing non-HRP2, *P. falciparum* specific targets will remain the same – valid ISO

13485:2003, application for WHO prequalification submitted, and acceptable performance indicators against both HRP2 expressing and HRP2 non-expressing (*pfhrp2/3* single or double deletions) based on the most recent WHO laboratory assessment. Data on performance against non-HRP2 expressing parasite panels is currently limited and varies depending on single or double deletions of *pfhrp2* and *pfhrp3* due to the cross reactivity of HRP3 with HRP2 test lines. Therefore, using these results to inform procurement and predict RDT performance in the field requires a detailed understanding of the local epidemiology and should be done in consultation with experts.

Generally, for areas with high prevalence of *pfhrp2/3* deletions, and where there is no need to distinguish between *P. falciparum* and non *falciparum* infections, pan-LDH only RDTs are the best option.

At present, no Pf-LDH based combination RDTs that aims to detect and distinguish between Pf and non-Pf infections meet WHO *P. falciparum* recommended panel detection score criteria on both low density (200 p/μL) HRP2 expressing and non-HRP2 expressing (mixed *pfhrp2*-/*pfhrp3*+ and *pfhrp2*-/*pfhrp3*-) *P. falciparum* panels. At higher parasite densities i.e. 2000 p/μL, all RDTs perform well (PDS >82%) against the panel of deleted *pfhrp2/3* parasites. These tests can be used as a survey tool to identify suspected *pfhrp2/3* deleted parasites but are not recommended for use in case management as they may lead to false negative results amongst low density (<2000p/μL), *pfhrp2* +/- 3 *P. falciparum* infections.

A full list of products evaluated between rounds 5–8 and their performance against HRP2 and non HRP2 expressing Pf panels at low and high density, *P. vivax* panels at low density and malaria negative samples is available in Annex 1.

Web-based interactive guide for the selection of malaria RDTs

For several years, FIND has maintained 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 5–8 of the product testing programme and can be found at: <http://www.rdt-interactive-guide.org/>. 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, who prequalification status 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

In rounds 1–8, RDTs submitted to WHO for testing were 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. In the future, an independent heat stability assessment will not be included as part of the WHO prequalification coordinated laboratory evaluation.

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

In rounds 1–8, RDTs submitted to WHO for testing were 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. Since round 7, reports include the product-specific frequency of anomalies found in the two lots submitted for testing. Overall rates are low. 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 requirements¹¹

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. 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. As protocol differences between RDTs can pose a challenge when new RDT brands are procured, categorization of products according to the same procedural characteristics was included in product testing reports (Annex 1) since round 6 and the interactive online guide has filter options, to help end users identify products with the same protocol. If similar products replace the previous ones, 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 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, ideally, after shipment, and in response to concerns/complaints post-deployment, at a lot-testing centre that collaborates with the WHO, as part of good procurement practice. In 2019, this service will remain free of charge at the Research Institute for Tropical Medicine (Philippines).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: https://www.finddx.org/wp-content/uploads/2017/08/Malaria-lot-testing-results-2007-endJune-2017_30AUG17.pdf.

WHO has commissioned annual independent, external quality laboratory assessments of the National Institute of Malaria Research (NIMR), New Delhi, India and the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos, Nigeria and these laboratories are compliant with WHO malaria RDT lot testing standard operating procedures. These laboratories will be conducting lot verification for RDT batches imported into their respective countries. Contact: India: anvikar@gmail.com; shbira@gmail.com; Nigeria: andimalariacentre@unilag.edu.ng

Role of recombinant antigen panels in lot testing

In 2018, the WHO-FIND RDT Evaluation Programme Steering Committee concluded that the HRP2 or pLDH recombinant antigen panels (manufactured by Microcoat: <https://www.microcoat.de/Products/recombinant-panels-for-malaria-diagnostic-tests/>) should not be used for malaria RDT lot testing purposes as some critical knowledge gaps on the panel characteristics remain. Also, data analysis showed that the lot testing procedure based on recombinant panels is not fully equivalent to the current one based on clinical samples.

Notes

1. This information note on recommended selection criteria for procurement of malaria rapid diagnostic tests replaces earlier versions released between 2009, 2016, 2017 and 2018 (January).
2. WHO guidelines for the treatment of malaria. Third edition. Geneva: World Health Organization; 2015 (<http://who.int/malaria/publications/atoz/9789241549127/en/>).
3. Universal access to malaria diagnostic testing – an operational manual. Geneva: World Health Organization; 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. Malaria rapid diagnostic test products: Suggested use of terms, requirements and preferences for labelling and instructions for use. Geneva: World Health Organization; 2017 (<http://who.int/malaria/publications/atoz/rdt-labelling-instructions-for-use/en/>).
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. Malaria rapid diagnostic test performance. Results of WHO product testing of malaria RDTs: round 7 (2015–2016). Geneva: World Health Organization–FIND; 2015 (<http://who.int/malaria/publications/atoz/978924151268/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. Good practices for selecting and procuring rapid diagnostic tests for malaria. Geneva: World Health Organization; 2011 (<http://who.int/malaria/publications/atoz/9789241501125/en/>).
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 5–8 OF WHO MALARIA RDT PRODUCT TESTING

The table below is based on Table S2 in the summary results of rounds 1–8 of WHO product testing of malaria RDTs (<https://apps.who.int/iris/bitstream/handle/10665/276193/9789241514958-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 5–8 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, two columns indicate if all WHO procurement criteria have been met against HRP2 expressing and non-expressing *P. falciparum* panels, as per the selection criteria described on page 3. If requirements for compulsory submission were not met, products were delisted and are not eligible for WHO 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 9–16, 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. A regularly updated list of WHO-prequalified diagnostics, including malaria RDTs, is available at http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/.

The lists of malaria RDTs included in this information note are not exhaustive. They include those products that were submitted for evaluation in rounds 5–8 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 WHO, or their evaluation has not yet been completed and published. This list and the WHO PQ assessment pipeline¹ are updated regularly.

Although updated evaluation results and public reports² are published by WHO, WHO cannot represent that products included in the lists will continue to meet the

procurement criteria in the same manner as indicated. WHO recommends, therefore, that before deploying malaria RDTs to the field, each lot of that product be tested at the Research Institute for Tropical Medicine, Philippines.³

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 9–16 of this information note.

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

Notes

1. http://www.who.int/diagnostics_laboratory/pq_status/en/
2. http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/
3. <https://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/evaluation-lot-testing/en/>

Performance of malaria RDTs in rounds 5-8 of the WHO malaria RDT product testing programme

Performance criteria (highlighted in green if met):

A: *P. falciparum* panel detection score (PDS)^a ≥ 75% at 200 parasites/μL

B: *P. vivax* panel detection score (PDS) α ≥ 75% at 200 parasites/μL

C: false-positive (FP) rate against clean negatives < 10%

D: invalid rate (IR) < 5%

E: *pfhrp2* negative *P.falciparum* panel detection score (PDS) > 75% at 200 parasites/μL (in areas where *pfhrp2* deletions are prevalent)

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS					MEETS WHO PROCUREMENT CRITERIA	P. FALCIPARUM HRP2 NON-EXPRESSING PANEL		MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND
			PDS ^a		IR	D ^e	E ⁱ		PDS	PF @2000p/μL		
			A ^b	B ^c								
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	80.0	NA	0.0	0.0	No			UK	7	
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	Inftec Products, Inc.	93.0	NA	0.4	0.0	No			UK	7	
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	0.0	0.0	No			UK	5	
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	98.0	NA	0.9 (231)	0.1	No			UK	7	
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd	93.0	NA	1.3	0.0	No			UK	7	
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote, Inc.	88.0	NA	0.5	0.0	No			UK	6	
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	97.0	NA	0.0	0.0	No			UK	7	
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	96.0	NA	0.4	0.0	No			UK	7	
CareStart™ Malaria Pf (HRP2) Ag RDT ^f	RMOM-02571	Access Bio Inc.	92.0	NA	0.0	0.1	Yes ^h	22.5		No	8	
CareStart™ Malaria Pf (HRP2/ pLDH) Ag Combo 3-line RDT ^{f, g}	RMSM-02571	Access Bio Inc.	82 (81/40) ^g	NA	0.5	0.0	No	12.5 (0/12.5) ^g	100	No	8	
CareStart™ Malaria Pf (HRP2/ pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	88.0	NA	0.0	0.0	No	17.5	100	No	8	
CareStart™ Malaria Pf (HRP2/ pLDH) Ag RDT ^f	RMPM-02571	Access Bio Inc.	96.0	NA	0.0	0.0	Yes ^h	60.0	100	No	8	
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	88.0	NA	0.0	0.0	No	22.5	100	No	8	
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	94.0	NA	0.9	0.0	No			UK	7	

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						MEETS WHO PROCUREMENT CRITERIA	P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND	
			PDS ^a			FP				IR	E ⁱ	PDS			PF @2000p/μL ^j
			A ^b	B ^c	C ^d	D ^e	F ^f	G ^g							
DIAQUICK Malaria Pf. Cassette	W06200	DIALAB	86.0	NA	0.0	0.0	0.0	No	UK			7			
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	10.0	NA	5.8	0.0	0.0	No	No	12.5	100	8			
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	71.0	NA	1.0	0.1	0.1	No	UK			6			
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	95.0	NA	0.4	0.0	0.0	Yes ^h	UK			5			
First Response® Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	1.0	0.0	0.0	Yes ^h	UK			6			
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	86.0	NA	0.4 (231)	0.1	0.1	No	UK			7			
Humasis Malaria P.f. Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	1.4	0.0	0.0	No	UK			6			
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	94.0	NA	1.7	0.0	0.0	No	UK			7			
IMMUNOQUICK® MALARIA falciparum	0502_K25	Biosynex	72.0	NA	5.1 (234)	0.2	0.2	No	UK			5			
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	85.0	NA	0.0	0.0	0.0	No	UK			7			
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	0.7	No	UK			5			
Malaria Antigen Test-Pf	MAG-01040	Oscar Medicare Pvt. Ltd.	91.0	NA	1.0	0.0	0.0	No	UK			6			
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	NA	0.0	0.1	0.1	No	UK			7			
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	93.0	NA	0.0	0.0	0.0	No	UK			7			
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	73.0	NA	0.0	0.0	0.0	No	UK			7			
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	75.0	NA	0.0	0.2	0.2	No	UK			6			
PALUTOP + pf®	5531	ALLDIAG SA	92.0	NA	0.0	0.0	0.0	No	UK			7			
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3) ⁱ	302030025	Orchid Biomedical Systems (Tulip Group)	94.0	NA	3.4 (207)	0.1	0.1	No	No	15.0		8			

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCEDURE CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND	
			PDS ^a			FP			IR	PDS	E ⁱ			PF @2000p/μL ^j
			A ^b	B ^c	C ^d	D ^e	F ^f	G ^g						
Paradhit® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd n	74.0	NA	0.0	0.0	0.0	0.0				UK	7	
Paradhit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd n	77.0	NA	0.0	0.0	0.0	0.0				UK	7	
Rapid 1-2-3® Hema® Cassette Malaria Pf	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	0.0	0.2						UK	6	
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	0.5 (207)	0.2						UK	6	
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	0.0	0.0						UK	6	
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) ^{f, g}	05FK90	Standard Diagnostics Inc. (Alerre)	90 (88/71) ^g	NA	0.0	0.1				32.5 (0/32.5) ^g	100	No	8	
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	90.0	NA	0.0 (231)	0.1						UK	7	
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	95.0	NA	0.0	0.0						UK	5	
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	87.0	NA	0.0	0.0				32.5		No	8	
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	93.0	NA	1.0	0.1				45.0		No	8	
PF AND PAN														
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						UK	5	
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Adv Chemical Private Limited	67.0	45.7	0.0	0.0						UK	7	
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	Inftec Products, Inc.	88.0	60.0	8.7 (231)	2.1						UK	5	
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	0.4	0.0						UK	5	
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	0.0	0.2						UK	5	
Alerre TrueLine™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alerre Medical Private Limited	85.0	91.4	0.0	0.0						UK	7	
Asan Easy Test® Malaria Pf/ Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	88.0	100.0	1.3	0.1						UK	7	

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						MEETS WHO PROCUREMENT CRITERIA	P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND
			PDS ^a		FP	IR	D ^e			E ⁱ	PDS	PF @2000p/μL ^j		
			A ^b	B ^c	C ^d	D ^e								
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	93.0	91.4	1.3 (231)	0.3	0.3	No			UK	7		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	90.0	22.9	0.0 (207)	0.2	0.2	No			UK	6		
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	91.0	100.0	3.9	0.0	0.0	No			UK	7		
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	83.0	68.6	0.5	0.0	0.0	No			UK	6		
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	85.0	85.7	0.0	0.0	0.0	No			UK	7		
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	96.0	97.1	0.9	0.0	0.0	No			UK	7		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	90.0	97.1	0.0	0.0	0.0	No	12.5		No	8		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT ^f	RMRM-02571	Access Bio Inc.	87.0	94.3	0.0	0.0	0.0	Yes ^h	7.5		No	8		
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT ^f	RMLM-02571	Access Bio Inc.	83.0	97.1	1.0	0.1	0.1	No ⁱ	0.0	82.5	No	8		
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	93.0	94.3	0.0 (231)	0.1	0.1	No			UK	7		
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	87.0	94.3	0.0	0.0	0.0	No	12.5		No	8		
DIAQUICK Malaria Pf/Pan Cassette	ZH200CE	DIALAB GmbH	90.0	82.9	2.1	0.2	0.2	No			UK	5		
Ecofest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	62.0	65.7	0.0	0.0	0.0	No	2.5		No	8		
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	1.4	0.0	0.0	No			UK	6		
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation Ltd.	85.0	74.3	0.0	0.0	0.0	No			UK	5		
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	1.9 (207)	0.1	0.1	Yes ^h			UK	6		
GenBody™ Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	0.0 (235)	0.2	0.2	No			UK	5		

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						MEETS WHO PROCUREMENT CRITERIA			P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM [™]	ROUND
			PDS ^a		FP	IR	D ^o		E ⁱ	PDS	PF @2000p/μL ^j	No	No	No		
			A ^b	B ^c	C ^d	D ^e										
Genedia® Malaria Pf/Pan Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	10.6	0.1	0.1	No			UK			5		
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	90.0	91.4	0.9 (235)	0.7	0.7	No			UK			5		
Humasis Malaria Pf/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	89.0	62.9	0.5	0.1	0.1	No			UK			6		
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	85.0	31.4	1.3	0.0	0.0	No			UK			7		
Is It... Malaria Pf/PAN	MPPPAN050	Medsourc Ozone Biomedicals Pvt. Ltd.	93.0	100.0	3.9	0.0	0.0	No			UK			7		
Is It... Malaria Pf/Pv Device	AL030	Medsourc Ozone Biomedicals	88.0	91.4	1.0 (206)	0.8	0.8	No			UK			6		
Malaria Pf./Pan Rapid Test Cassette ^f	IMPAN-402	Hangzhou AllTest Biotech Co. Ltd.	63.0	91.4	0.5	0.0	0.0	No	0.0		No	0.0		8		
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	41.0	8.6	81.3 (235)	0.1	0.1	No			UK			5		
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	0.9	0.2	0.2	No			UK			5		
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	0.4 (232)	1.0	1.0	No			UK			5		
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	83.0	100.0	1.4	0.1	0.1	No	7.5		No			8		
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	27.0	100.0	1.0	0.0	0.0	No	10.0	100	No			8		
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	15.3	0.1	0.1	No			UK			5		
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	92.0	25.7	33.2	0.2	0.2	No			UK			7		
One Step Malaria Pf/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	77.0	14.3	0.0	0.0	0.0	No			UK			6		
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	78.0	85.7	0.0 (207)	0.2	0.2	No			UK			6		
Parascreen® Rapid Test for Malaria Pan/Pf ^f	503030025	Zephyr Biomedicals	91.0	94.3	0.5	0.0	0.0	No	0.0		No			8		
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	7.2	0.1	0.1	No			UK			6		

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						MEETS WHO PROCUREMENT CRITERIA	P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND
			PDS ^a		FP	IR	PDS			E ⁱ	PF @2000p/μL ^j			
			A ^b	B ^c	C ^d	D ^e								
Rapid 1-2-3 HEMA® CASSETTE MALARIA Pf/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	92.0	100.0	0.4	0.0	0.0	No			UK	7		
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	74.0	40.0	14.0	0.0	0.0	No			UK	5		
SD BIOLINE Malaria Ag P.f./Pan	05FK60	Standard Diagnostics Inc.	94.0	91.4	0.0	0.0	0.0	Yes ^h			UK	5		
STANDARD Q Malaria P.f./Pan Ag Test	09MAL30B	SD Biosensor	88.0	100.0	0.0	0.0	0.0	No	32.5		No	8		
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	1.3 (235)	0.3	0.3	No			UK	5		
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	92.0	80.0	10.6	0.2	0.2	No	35.0		No	8		
Pf and Pv/Pvom														
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	92.0	97.1	0.4	0.1	0.1	No			UK	7		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	86.0	85.7	0.0	0.1	0.1	No	32.5		No	8		
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	G60RHA25	RapiGEN Inc.	75.0	100.0	0.0 (230)	0.6	0.6	Yes ⁱ			UK	7		
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	85.0	91.4	0.0 (229)	0.3	0.3	No			UK	7		
BioTracer™ Malaria P.f./Pv Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	0.0	0.1	0.1	No			UK	6		
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	91.0	97.1	0.0	0.0	0.0	No			UK	7		
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT ^f	RMVM-02571	Access Bio Inc.	87.0	100.0	0.0	0.0	0.0	Yes ^h	10.0		No	8		
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT ^f	RMWM-02571	Access Bio Inc.	87.0	100.0	0.0	0.0	0.0	No	10.0		No	8		
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	93.0	88.6	0.0	0.0	0.0	No			UK	7		
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	0.5	No			UK	6		
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	88.0	74.3	0.0	0.1	0.1	No	25.0		No	8		

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE PANELS						MEETS WHO PROCUREMENT CRITERIA	P. FALCIPARUM HRP2 NON-EXPRESSING PANEL			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND
			PDS ^a		FP	IR	D ^e			E ⁱ	PDS	PF @2000p/μL ^j		
			A ^b	B ^c	C ^d	D ^e								
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	3.9	0.0	0.0	No			UK	6		
FalciVax™ Rapid Test for Malaria Pv/Pf ^f	503010025	Zephyr Biomedicals	95.0	100.0	0.5	0.0	0.0	No	0.0		No	8		
First Response® Malaria Ag. P.f./P.v. Card test ^f	PI19FRC25	Premier Medical Corporation Private Ltd.	94.0	100.0	1.0	0.1	0.1	Yes ^h	12.5		No	8		
Humasis Malaria P.f./P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	88.0	91.4	1.0 (207)	0.1	0.1	No			UK	6		
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW I550E	Karwa Enterprises Pvt. Ltd.	83.0	77.1	1.9	0.0	0.0	No	35.0		No	8		
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	0.0	No			UK	6		
Malaria Pf (HRP11)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	0.9 (232)	2.5	2.5	No			UK	5		
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	57.1	0.0 (231)	0.3	0.3	No			UK	7		
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	90.0	51.4	0.0 (203)	1.3	1.3	No			UK	6		
Maleriscan® Malaria Pf/PAN (Pv, Pm, Pc) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	3.0 (232)	0.7	0.7	No			UK	5		
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	88.0	91.4	0 (201)	0.7	0.7	No	32.5		No	8		
One Step Malaria HRP2/pLDH (P.f./P.v.) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	92.0	65.7	1.3	0.0	0.0	No			UK	7		
One Step Malaria P.F./P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	77.1	0.0	0.0	No			UK	5		
One Step Test for Malaria Pf/ Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	78.0	85.7	0.0	0.0	0.0	Yes ^h			UK	7		
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	74.0	80.0	0.0 (207)	0.2	0.2	No			UK	6		
ParaHT® IV Rapid test for P. falciparum and P.vivax Malaria - Device	551C402-50	ARKRAY Healthcare Pvt. Ltd.n	63.0	37.1	6.4	0.1	0.1	No			UK	5		

PRODUCT	PRODUCT CODE	MANUFACTURER	P. FALCIPARUM HRP2 EXPRESSING, P. VIVAX AND MALARIA NEGATIVE						P. FALCIPARUM HRP2 NON-EXPRESSING			MEETS WHO PROCUREMENT CRITERIA FOR DETECTION OF PFHRP2/3 DELETED P. FALCIPARUM ^m	ROUND
			PANELS			MEETS WHO PROCUREMENT CRITERIA			PANEL		PF @2000p/μL ^j		
			PDS ^a	FP	IR	A ^b	B ^c	C ^d	D ^e	E ⁱ			
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	79.0	88.6	22.9 (231)	0.1	No				UK	7	
Rapid Test Kit for Malaria Ag Pf/Pv - Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	85.0	88.6	0.0	0.0	No				UK	7	
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	4.4 (207)	0.2	No				UK	6	
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	92.0	94.3	1.9	0.0	Yes ^h				UK	6	
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	85.0	100.0	0.0	0.0	No	25.0			No	8	
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	84.0	80.0	31.7	0.0	No	20.0			No	8	
PF, PF AND PV													
SD BIOLINE Malaria Ag P.f/P.f/P.v ^{f,g}	05FK120	Standard Diagnostics Inc. (Alere)	89 (89/62) ^g	97.1	0.0	0.0	Yes ^h	20 (0/20) ^g	100		No	8	
PF, PV AND PAN													
PALUTOP +4 optima®	5499	ALLDIAG SA	91.0	82.9 ^p	0.0	0.0	No				UK	7	
PAN ONLY													
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	0.4	0.0	Yes				UK	5	
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02571	Access Bio, Inc.	84.0	88.6	0.0	0.0	Yes ^h	100 ^k	100 ⁱ		Yes	5 ^{k,l}	
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	98.0	97.1	9.1	0.0	Yes	90.0			Yes	8	
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	98.0	85.7	5.3	0.0	Yes	85.0			Yes	8	

Notes

Pf, *Plasmodium falciparum*

Pv, *Plasmodium vivax*

pan, *Plasmodium* species

Pvom, *Plasmodium vivax, ovale* and *malariae*

- a A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive
- b Round 1, n=79; Round 2, n=100; Round 3, n=99; Round 4, n=98; Round 5, n=100; Round 6, n=100; Round 7, n=100; Round 8, n=100
- c Round 1, n=20; Round 2, n=40; Round 3, n=35; Round 4, n=34; Round 5, n=35; Round 6, n=35; Round 7, n=35; Round 8, n=35
- d Round 1, n=168; Round 2, n=200; Round 3, n=200; Round 4, n=232; Round 5, n=236; Round 6, n=208; Round 7, n=220; Round 8, n=208
- e Round 1, n=954; Round 2, n=1240; Round 3, n=1204; Round 4, n=1192; Round 5, n=1214 ; Round 6, n=1210; Round 7, n=1210; Round 8, n=1210
- f Product resubmission in round 8. Results from round 8 replace previous results.
- g PDS presented in the table is based on a positive Pf test line (either HRP2 or Pf-LDH). The results in brackets are the PDS based alone on HRP2 and Pf-LDH test lines, respectively.
- h Indicates a WHO prequalified product
- i Round 8, n=40 (18 double deletion: *pfhrp2-/pfhrp3-*; 22 single deletion; *pfhrp2-/pfhrp3+*)
- j Results (PDS) of adhoc assessment of pLDH containing round 8 RDTs against high density HRP2 negative panel : n=40 (18 double deletion: *pfhrp2-/pfhrp3-*; 22 single deletion; *pfhrp2-/pfhrp3+*)
- k Results (PDS) of adhoc assessment of this product against the round 8 low density HRP2 negative panel n=40 (18 low density double deletion: *pfhrp2-/pfhrp3-*; 22 single deletion; *pfhrp2-/ pfhrp3+*)
- l Results (PDS) of adhoc assessment of this product against a high density HRP2 negative panel n=40 (18 low density double deletion: *pfhrp2-/pfhrp3-*; 22 single deletion; *pfhrp2-/pfhrp3+*)
- m These results should be considered when procuring RDT for use in areas where *pfhrp2+* or *- pfhrp3* deletions are prevalent.