



# Malaria Rapid Diagnostic Test Performance

Summary results of WHO Malaria RDT  
Product Testing: Rounds 1-3 (2008-2011)



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TDR/RDT/11.1

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# 1. SUMMARY PERFORMANCE OF MALARIA RDTs: WHO PRODUCT TESTING: ROUNDS 1-3

## 1.1. Introduction

The World Health Organization estimates that half the world's population are at risk of malaria, with 225 million people developing clinical malaria in 2009 (78% in Africa), and 781,000 deaths (91% in Africa, most being children). Malaria remains endemic in 106 countries, and while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly identified, resulting in over-use of anti-malarial drugs and poor disease monitoring.<sup>1</sup>

WHO recommends that malaria case management be based on parasite-based diagnosis in all cases<sup>2</sup>. The use of antigen-detecting rapid diagnostic tests (RDTs) forms a vital part of this strategy, forming the backbone of expansion of access to malaria diagnosis as they provide parasite-based diagnosis in areas where good quality microscopy cannot be maintained. The number of RDTs available, and the scale of their use, has rapidly increased over the past few years. However, limitations of comparative field trials and the heterogeneous nature of malaria transmission and epidemiology has limited the availability of good quality performance data that national malaria programmes require to make informed decisions on procurement and implementation, and limits the ability to extrapolate results of field trials to different populations and time periods. To this end in 2006, the World Health Organization (WHO), Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched an evaluation programme to assess the comparative performance of commercially available malaria RDTs. This data is guiding procurement decisions and helping to drive improvement in the quality of manufacturing. The results of the first and second rounds of Product Testing were published in 2009 and 2010, and now form the basis of procurement criteria of WHO and UN agencies and national governments.

This Summary presents an overview of the results of the first, second and third rounds of WHO Product Testing of malaria antigen-detecting RDTs completed in 2008, 2009 and 2011 respectively, and is published in conjunction with the release of the results of Round 3. The results of the three rounds of testing should be considered as a single data set. Concerning products re-submitted for evaluation, the results of earlier rounds are replaced by subsequent rounds and therefore only one set of results per product feature in

this summary. Separate full reports of all rounds should be consulted for further detail on product performance, and on the interpretation and use of these results.

## 1.2. The WHO Product Testing Programme

The RDT evaluations summarized here were performed as a collaboration between WHO, TDR, FIND, the US Centers for Disease Control and Prevention (CDC) and other partners<sup>3</sup>. All companies manufacturing under ISO 13485:2003 Quality System Standard were invited to submit up to 3 tests for evaluation under the programme. In the first round of testing, 41 products from 21 manufacturers were evaluated against prepared blood panels of cultured *Plasmodium falciparum* parasites, while 29 products from 13 manufacturers were evaluated in Round 2. In Round 3, 50 products were evaluated from 23 manufacturers, including 23 products re-submitted from earlier rounds (Table S3). Of these 120 total products, 118 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites, and a parasite-negative panel. Thermal stability was assessed after two months of storage at elevated temperature and humidity, and a descriptive ease of use assessment was recorded. Of the 118 fully evaluated products, 25 have been evaluated in more than one round. Of the 95 unique products tested by the programme, 29 detect *P. falciparum* alone, 57 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific), 8 detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them, and one product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation. Where the same products<sup>4</sup> have been re-submitted in subsequent rounds of testing, the latter results replace results published from the earlier round. Thus, the performance of many tests in the results below differ from those published in the Round 1 and Round 2 reports.

The evaluation is designed to provide comparative data on the performance of the submitted production lots of each product. Such data will be used to guide procurement decisions of WHO and other UN agencies and national governments. Product testing is part of a continuing programme of work to improve the quality of RDTs that are used, and to support broad implementation of reliable malaria diagnosis in areas where malaria is prevalent. A fourth round of product testing began in June 2011.

<sup>1</sup> World Malaria Report 2010. Geneva, World Health Organization, 2010.

<sup>2</sup> Guidelines for the Treatment of Malaria, Second Edition. Geneva, World Health Organization, 2010.

<sup>3</sup> See full reports of Rounds 1, 2 and 3 for full list of collaborating partners.

<sup>4</sup> Working definition of a product can be found here on page 13: [http://www.wpro.who.int/internet/resources.ashx/RDT/docs/pdf\\_version/web3\\_QARDTreport.pdf](http://www.wpro.who.int/internet/resources.ashx/RDT/docs/pdf_version/web3_QARDTreport.pdf) (accessed 8 September 2011)

### 1.3. Results of the evaluation

The results (summarized in Figures S1 and S2 and Tables S1 and S2) provide comparative data on two lots of products against a panel of parasite samples diluted to a low parasite density (200 parasites/μl) and a higher parasite density (2000 or 5000 parasites/μl). The former is well below the mean parasite density found in many populations with endemic malaria, and considered close to the threshold that tests must detect to reliably identify clinical malaria in many settings.<sup>5</sup> For the purposes of this report, the main measure of performance is the 'panel detection score (PDS)'<sup>6</sup>; the percentage of malaria samples in the panel giving a positive result by two RDTs per lot at the lower parasite density, and a single RDT per lot at the higher parasite density. Thus, it is not a measure of RDT clinical sensitivity, or positivity rate against the panel but rather a combined measure of positivity rate, along with inter-test and inter-lot consistency. The figures also show the false-positive rates against blood samples containing no malaria parasites or known markers of other diseases, and the rate at which invalid results occurred.

The clinical sensitivity of an RDT to detect malaria is highly dependent on the local conditions, including parasite density in the target population. Sensitivity of a test will therefore differ between populations with differing levels of transmission, as their different level of immunity will affect the parasite density at which they exhibit symptoms warranting a diagnostic test. Where transmission rates are low, parasite densities in people with symptoms of malaria are likely to be lower, resulting in tests having a lower sensitivity. For this reason, test performance at 200 parasites/μl is particularly important. The results in this report show comparative performance between RDTs, and give an indication of which products are likely to provide higher sensitivity in the field, particularly in populations with low-density infections. In general, as countries reduce malaria prevalence and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the detection rate at 2000 parasites/μl indicates, the sensitivity of many of these products will be similar in populations with higher parasite densities, although a subset of any population will include vulnerable individuals who may develop illness at low parasite densities (e.g. young children, pregnant women, those well protected by bed nets) and must always be taken into account when interpreting RDT results. An important caveat when predicting field sensitivity from the PDS provided in this report is that the panels used in this evaluation only include parasites known to express the target antigens. While non-expression of the target antigens has not been recorded for aldolase or pLDH, it is known that parasites infecting people in some areas of South America do not express HRP2<sup>7</sup>. In areas where HRP2-deleted parasites exist, HRP2-detecting

tests will have greatly reduced sensitivity or be incapable of detecting *P. falciparum*. In such populations, only tests detecting pLDH in *P. falciparum* parasites will be effective in diagnosing falciparum malaria.

Heat stability (summarized in Table S2) is vital to maintaining sensitivity of the test in the field. As a result, for procurement, it is essential that careful consideration be given to stability results to ensure that products to be used in areas with high temperatures of transport and storage have demonstrated stability in the product testing programme. Requirements will vary between countries: for example, if tests are to be deployed in areas where temperatures rarely rise above 30°C, less emphasis may be placed on stability at high temperatures compared to other aspects of test quality.

Ease of use requirements will also vary, depending on the extent of training and the work environment of the end-users. Particularly in primary health care settings, the simpler the tests, the easier it will be to avoid errors in preparation and interpretation.

Detailed results of the evaluations can be found in the reports of each evaluation,<sup>8</sup> and at [www.wpro.who.int/sites/rdt](http://www.wpro.who.int/sites/rdt). An interactive guide to assist in selecting products with performance characteristics most suitable for a particular country health programme is found on the FIND website.<sup>9</sup>

<sup>5</sup> *Parasitological Confirmation of Malaria Diagnosis*. Report of a WHO technical consultation Geneva, 6–8 October 2009. Geneva, World Health Organization, 2010. ISBN 978 92 4 159941 2

<sup>6</sup> Termed 'Detection Rate' in the full report of Round 1, published in 2009. See the Round 3 report for a full explanation of the panel detection score (PDS).

<sup>7</sup> Gamboa D et al. *PLoS One*, 2010; 5(1): e8091

<sup>8</sup> *Malaria Rapid Diagnostic Test Performance : Results of WHO product testing of malaria RDTs: Round 1 (2008)*. Geneva, World Health Organization, 2009. ISBN 978 92 4 1598071; *Malaria Rapid Diagnostic Test Performance : Results of WHO product testing of malaria RDTs: Round 2 (2009)*. Geneva, World Health Organization, 2010. ISBN 978 92 4 1599467

<sup>9</sup> Malaria RDT Interactive Guide : [http://www.finddiagnostics.org/programs/malaria/find\\_activities/product\\_testing/malaria-rdt-product-testing/index.jsp](http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing/index.jsp) (accessed 8 Sept.2011)

## 1.4. Summary of outcomes

This laboratory-based evaluation provides a comparative measure of RDT performance in a standardized way to distinguish between well and poorly performing tests to inform procurement decisions of malaria control programmes and guide UN procurement policy.

Overall, an improvement was noted in the performance of products re-submitted to Round 3 (Table S3), indicating product improvement by the manufacturers. Furthermore, the proportion of tests achieving a PDS (>75%) at 200 parasites/μl is higher than that seen in previous reports.

Several RDTs from the three rounds of testing demonstrated consistent detection of malaria at low parasite densities (200 parasites/μl), have low false positive rates, are stable at tropical temperatures, are relatively easy to use, and can detect *P. falciparum*, *P. vivax* infections, or both.

Performance between products varied widely at low parasite density (200 parasites/μl); however, the majority of products showed a high level of detection at 2000 or 5000 parasites/μl.

*P. falciparum* tests targeting HRP2 antigen demonstrated the highest detection rates, but some tests targeting pLDH also exhibited high detection rates.

Test performance varied between lots, and widely between similar products, confirming the advisability of lot-testing post-purchase and prior to use in the field.

The results underscore the need for manufacturers to have adequate reference materials for product development and lot-release. The WHO-FIND Malaria RDT Evaluation Programme, in collaboration with the CDC, offers quality standard panels to manufacturers to assist in this process.

## 1.5. Use of these results

Accurate diagnosis is vital to good malaria case management, whether based on microscopy or RDTs. The results of this report should be used to short-list RDTs for procurement for use in cases where good microscopy is not available or appropriate. Additionally, it is imperative that procurement decisions based on these results take into consideration local conditions of malaria transmission and illness where the tests will be used (e.g. *Plasmodium* species, target antigen variation, parasite densities, climate), as well as other important considerations, including field-based ease of use assessments, and training/retraining requirements. Furthermore, in order to ensure that the high performance demonstrated by the lots evaluated in the product testing programme is maintained, it is recommended that each lot of RDTs is also tested in a standardized way prior to dispersal to the field.<sup>10</sup> Procurement of RDTs must not occur without programmatic and infrastructure preparation for proper use, including supply chain management, training on test usage and disposal, and training on patient management in response to results. The main report provides an algorithm (Annex 5a) to assist in this decision-making process and comprehensive guidance on several aspects of procurement can be found in 'Good Practices for selecting and procuring rapid diagnostic tests for malaria'.<sup>11</sup>

<sup>10</sup> The WHO-FIND Malaria RDT Evaluation Programme provides lot-testing capacity in a number of regional laboratories free of charge, and can be accessed through [Malaria\\_rdt@who.int](mailto:Malaria_rdt@who.int) and [info@finddiagnostics.org](mailto:info@finddiagnostics.org).

<sup>11</sup> Good Practices for selecting and procuring rapid diagnostic tests for malaria, Geneva, World Health Organization, 2011 ISBN 9789241501125

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Figure S1: Malaria RDT performance in Phase 2 of Rounds 1–3 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000 or 5000) parasite densities (parasites/μl) and clean-negative samples

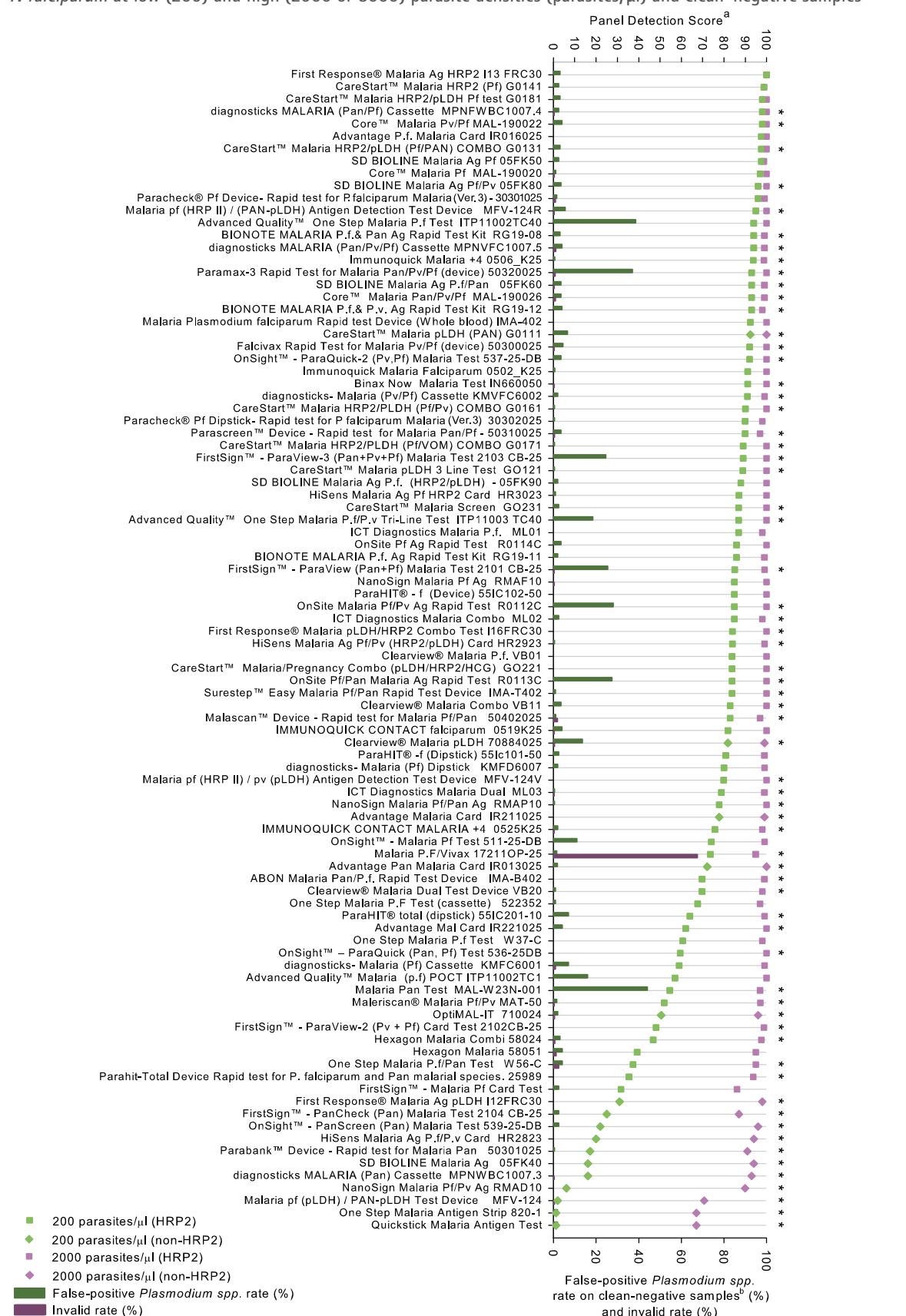




Figure S2: Malaria RDT performance in Phase 2 of Rounds 1–3 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000 or 5000) parasite densities (parasites/μl) and clean-negative samples

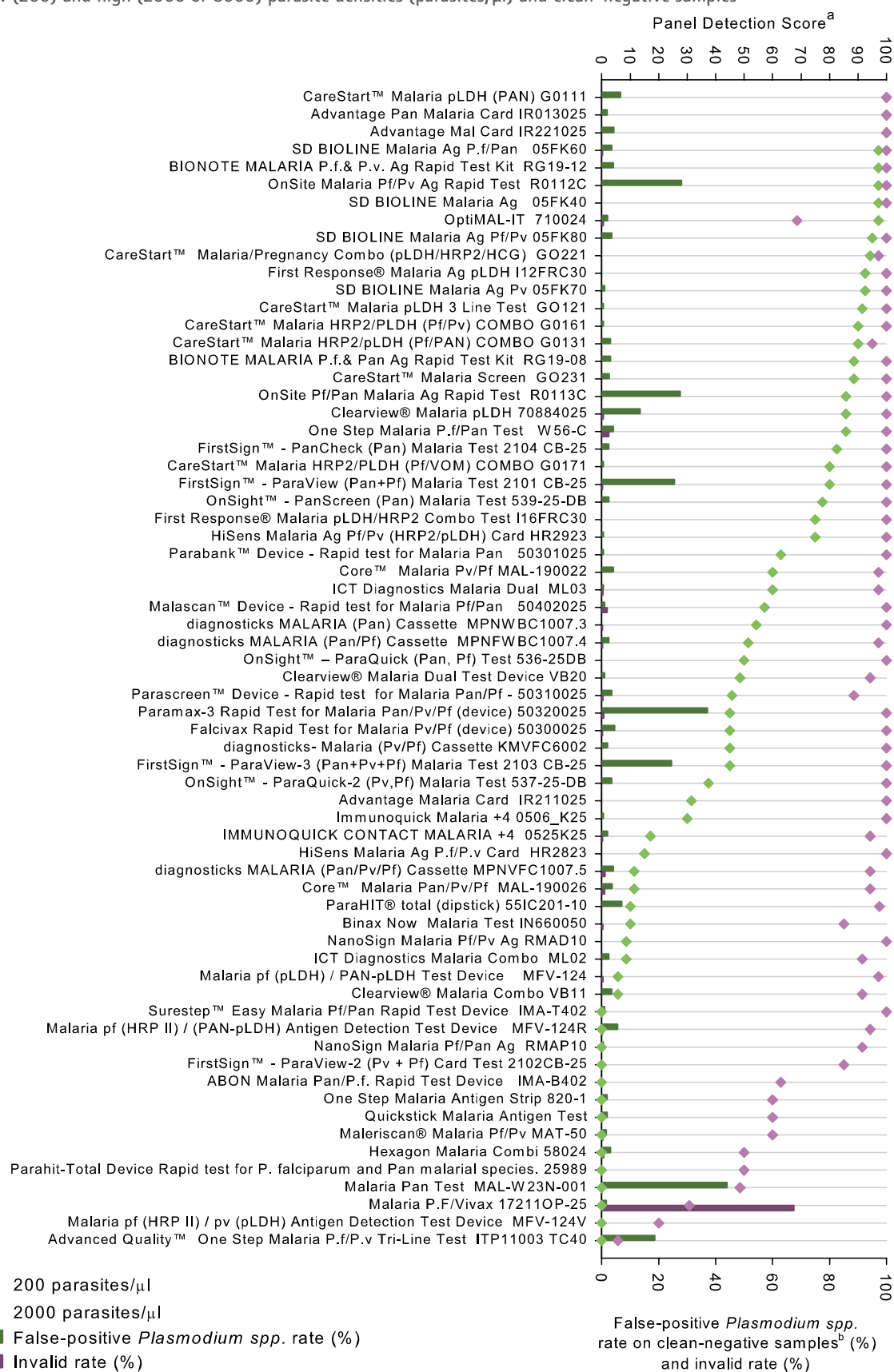


Table S1: Malaria RDT Phase 2 performance in Rounds 1–3 against wild type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) and high (2000 or 5000) parasite densities (parasites/μl) and clean negative samples

Product	Catalogue number	Manufacturer	Panel Detection Score <sup>a</sup>				False positive rates (%)						Total false positive rates <sup>b</sup> (%)		Invalid rate (%) (n=1204)	Round	
			200 parasites/μl		2000 or 5000 parasites/μl		200 parasites/μl		2000 or 5000 parasites/μl		Clean-negative samples		False positive <i>Plasmodium spp.</i> Infection <sup>i</sup>				
			Pf samples <sup>c</sup>	Pv samples <sup>d</sup>	Pf samples <sup>e</sup>	Pv samples <sup>f</sup>	Pf samples	False positive non-Pf infection <sup>e</sup>	False positive non-Pf infection <sup>f</sup>	Pf samples	False positive non-Pf infection <sup>g</sup>	False positive Pf samples					
Pf only																	
Advanced Quality™ One-Step Malaria Pf Test <sup>j</sup>	ITP11002TC40	InTec Products, Inc.	93.9	N/A	100.0	N/A	N/A	40.0	N/A	N/A	35.7	38.5	0.1	3			
Advanced Quality™ Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	57.0	N/A	100.0	N/A	N/A	12.5	N/A	N/A	17.5	16.1	0.0	1			
Advantage Pf. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	97.5	N/A	100.0	N/A	N/A	1.3	N/A	N/A	2.5	0.0	0.0	1			
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote, Inc.	85.9	N/A	99.0	N/A	N/A	0.0	N/A	N/A	1.4	2.0	0.1	3			
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	98.7	N/A	98.7	N/A	N/A	5.0	N/A	N/A	7.5	2.4	0.0	1			
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	N/A	100.0	N/A	N/A	0.6	N/A	N/A	1.3	3.0	0.0	2			
Clearview® Malaria P.f <sup>j</sup>	VB01	Vision Biotech (Pty) Ltd	83.8	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	0.0	0.0	3			
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	1.0 (198)	0.3	3			
diagnostics- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	59.0	N/A	99.0	N/A	N/A	1.9	N/A	N/A	2.6 (77)	7.0	0.9	2			
diagnostics- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	N/A	99.0	N/A	N/A	2.5	N/A	N/A	3.8	2.0	0.0	2			
First Response® Malaria Ag HRP2	I13RRC30	Premier Medical Corporation Ltd.	100.0	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	3.0	0.0	1			
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	31.7	N/A	86.1	N/A	N/A	12.5	N/A	N/A	15.0	2.4 (166)	0.0	1			
Hexagon Malaria	58051	Human GmbH	39.2	N/A	94.9	N/A	N/A	7.9 (76)	N/A	N/A	2.5	4.2 (167)	1.2	1			
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	87.0	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	1.0	0.1	2			
ICT Diagnostics Malaria P.f <sup>j</sup>	ML01	ICT Diagnostics	86.9	N/A	98.0	N/A	N/A	0.0	N/A	N/A	0.0	0.0	0.0	3			
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	N/A	100.0	N/A	N/A	3.6 (139)	N/A	N/A	1.4	4.0 (199)	0.3	3			
Immunquick Malaria Falciparum	0502_K25	Biosynex	91.1	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	0.6	0.0	1			
Malaria <i>Plasmodium falciparum</i> Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	92.4	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	0.0	0.0	1			
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	0.0	0.3	3			
One Step Malaria Pf Test (cassette) <sup>j</sup>	522352	Blue Cross Bio-Medical (Beijing) Co. Ltd.	67.7	N/A	97.0	N/A	N/A	0.0	N/A	N/A	2.9	1.0	0.2	3			
One Step Malaria Pf Test <sup>j</sup>	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	60.6	N/A	98.0	N/A	N/A	0.7 (139)	N/A	N/A	0.0	0.0	0.2	3			
OnSite™ – Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	N/A	99.0	N/A	N/A	8.1	N/A	N/A	2.5	11.0	0.0	2			
OnSite Pf Ag Rapid Test <sup>j</sup>	R0114C	CTK Biotech, Inc.	85.9	N/A	100.0	N/A	N/A	0.7	N/A	N/A	0.0	3.5	0.0	3			
Paracheck® Pf Device- Rapid test for <i>P. falciparum</i> Malaria Ver. 3 <sup>j</sup>	30301025	Orchid Biomedical Systems	96.0	N/A	99.0	N/A	N/A	0.0 (138)	N/A	N/A	1.5 (68)	1.5	0.9	3			
Paracheck® Pf Dipstick- Rapid test for <i>P. falciparum</i> Malaria Ver. 3 <sup>j</sup>	30302025	Orchid Biomedical Systems	89.9	N/A	98.0	N/A	N/A	0.0	N/A	N/A	1.4	0.5	0.0	3			
ParaHit® – f (Device) <sup>j</sup>	551C102-50	Span Diagnostics Ltd.	84.9	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	0.0	0.0	3			
ParaHit® – f (Dipstick) <sup>j</sup>	551C101-50	Span Diagnostics Ltd.	80.8	N/A	99.0	N/A	N/A	0.0	N/A	N/A	1.4	2.5	0.0	3			
SD BIOLINE Malaria Ag Pf. (HRP2/pLDH) <sup>k</sup>	05FK90	Standard Diagnostics Inc.	87.9	N/A	100.0	N/A	N/A	0.0	N/A	N/A	0.0	2.0	0.0	3			
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	97.5	N/A	98.7	N/A	N/A	0.0	N/A	N/A	0.0	2.4	0.0	1			
Pf and Pan																	
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	69.7	0.0	99.0	62.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3			
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	62.0	100.0	100.0	100.0	2.5	0.0	0.0	0.0	0.0	4.2	0.0	1			
Binox Now Malaria Test	IN660050	Inverness Medical Innovations, Inc.	91.1	10.0	100.0	85.0	0.3	3.8 (79)	0.0 (157)	5.0	0.0	0.0	0.3	1			
BIONOTE MALARIA P.f&t Pan Ag Rapid Test Kit	RG19-08	Bionote, Inc.	93.9	88.6	99.0	100.0	0.0	0.0	0.0	0.0	0.0	3.0 (199)	0.1	3			
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	100.0	97.1	2.3	1.4 (139)	0.0 (194)	1.4	0.0	0.0	0.2	3			
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131	Access Bio, Inc.	97.5	90.0	100.0	95.0	0.3	1.3	0.0	2.5	3.0	0.0	0.0	1			
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	100.0	100.0	1.3	0.7	6.1	0.0	0.5	0.0	0.0	3			
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	100.0	100.0	1.8	2.1	0.0	0.0	2.5 (199)	0.1	0.1	3			

Product	Catalogue number	Manufacturer	Panel Detection Score <sup>a</sup>				False positive rates (%)						Total false positive rates <sup>b</sup> (%)		Invalid rate (%) (n=1204)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples	False positive <i>Plasmodium spp.</i> Infection <sup>i</sup>				
			Pf samples <sup>c</sup>	Pv samples <sup>d</sup>	Pf samples <sup>e</sup>	Pv samples <sup>f</sup>	Pf samples	Pv samples	False positive non-Pf infection <sup>g</sup>	False positive Pf infection <sup>h</sup>						
Clearview® Malaria Combo <sup>j</sup>	VB11	Vision Biotech (Pty) Ltd	82.8	5.7	100.0	91.4	0.0	5.7	0.5	5.7	3.5	0.0	0.0	3	3	
Clearview® Malaria Dual Test Device <sup>j</sup>	VB20	Vision Biotech (Pty) Ltd	69.7	48.6	98.0	94.3	0.0	0.7 (139)	0.0	1.4	1.0	0.2	0.0	0.2	3	3
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	98.0	51.4	100.0	97.1	0.0 (394)	0.0	0.0	0.0 (69)	2.5	0.3	0.0	0.3	3	3
First Response® Malaria pLDH/HRP2 Combo Test <sup>j</sup>	116FR30	Premier Medical Corporation Ltd.	84.0	75.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2	2
FirstSign™ – ParaView (Pan+Pf) Malaria Test	2101 CB-25	Unimed International Inc.	85.0	80.0	99.0	100.0	0.0	0.6 (159)	0.5 (199)	0.0	25.5	0.2	0.0	0.2	2	2
Hexagon Malaria Kombi	58024	Human GmbH	46.8	0.0	97.5	50.0	0.0	0.0 (79)	0.0 (157)	2.6 (38)	3.0 (167)	0.7	0.0	0.7	1	1
HiSens Malaria Ag Pf/Pv Card	HR2823	HBI Co., Ltd.	20.0	15.0	94.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	84.0	75.0	99.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0	0.0	0.0	2	2
ICT Diagnostics Malaria Combo <sup>j</sup>	ML02	ICT Diagnostics	84.9	8.6	98.0	91.4	0.0	3.6	0.0	5.7	2.5	0.0	0.0	0.0	3	3
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	78.8	60.0	99.0	97.1	0.5 (394)	0.0	0.0	1.4	0.5 (199)	0.3	0.0	0.3	3	3
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	98.0	94.3	1.8 (395)	5.1 (138)	0.0	0.0	2.0	0.3	0.0	0.3	3	3
Immunoquick Malaria +4	0506_K25	Biosynex	93.7	30.0	98.7	100.0	0.0 (314)	0.0	0.0 (157)	0.0	0.6	0.0	0.0	0.0	1	1
Malaria Pf/Vvax	172110P-25	Diagnostics Automation/Cortez Diagnostics, Inc.	73.6 (53)	0.0 (15)	94.9 (39)	30.8 (13)	1.0 (97)	0.0 (30)	2.1 (48)	0.0 (18)	1.6 (64)	67.5	0.0	67.5	1	1
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	54.6	0.0	97.0	48.6	2.8	15.7	0.0	17.1	44.0	0.0	0.0	0.0	3	3
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device <sup>j</sup>	MFV-124R	AZOG, Inc.	95.0	0.0	100.0	94.3	0.0 (395)	7.9	8.1	0.0	5.5 (199)	0.3	0.0	0.3	3	3
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	2.0	5.7	70.7	97.1	0.0 (394)	0.0 (139)	0.0	0.0	0.0 (198)	0.4	0.0	0.4	3	3
Malascan™ Device - Rapid test for Malaria Pf/Pan <sup>j</sup>	50402025	Zephyr Biomedical Systems	82.8	57.1	97.0	100.0	1.0 (392)	0.7 (136)	1.0 (194)	0.0 (68)	1.0 (195)	1.9	0.0	1.9	3	3
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	77.8	0.0	100.0	91.4	0.0	2.9	0.0 (197)	2.9	0.5	0.0	0.0	0.0	3	3
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	6.1	8.6	89.9	100.0	0.5	0.0 (139)	0.0	0.0	0.0	0.1	0.0	0.1	3	3
One Step Malaria Antigen Strip	820-1	IND Diagnostic Inc.	1.3	0.0	67.1	60.0	2.2	3.8	1.9	0.0	1.8 (167)	0.0	0.0	0.0	1	1
One Step Malaria P.f/Pan Test <sup>j</sup>	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	37.4	85.7	95.0	100.0	8.4 (383)	0.0 (137)	0.0 (194)	0.0 (68)	4.1 (195)	2.4	0.0	2.4	3	3
OnSite™ – ParaQuick (Pan, Pf) Test	536-25DB	Amgenix International, Inc.	59.5	50.0	100.0	100.0	0.0	1.3	0.0	0.0	0.0	0.0	0.0	0.0	1	1
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	83.8	85.7	100.0	100.0	1.3	0.0	0.0	0.0	27.5	0.0	0.0	0.0	3	3
OptiMAL-IT	710024	Diamed – A Division of Bio-Rad	50.5	97.1	96.0	68.6	1.5	0.0	0.5	20.3 (69)	2.0 (198)	0.5	0.0	0.5	3	3
ParaHit® total (dipstick)	55IC201-10	Span Diagnostics Ltd	64.0	10.0	99.0	97.5	0.0	0.0	0.0	0.0	7.0	0.0	0.0	0.0	2	2
Parahit-Total Device Rapid test for <i>P. falciparum</i> and Pan malarial species.	25989	Span Diagnostics Ltd.	35.4	0.0	93.7	50.0	0.0 (315)	0.0	0.0	2.5	0.0	0.2	0.0	0.2	1	1
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	89.9	45.7	97.0	88.6	1.0 (394)	2.1	0.0 (197)	7.1	3.5 (199)	0.4	0.0	0.4	3	3
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.	1.3	0.0	67.1	60.0	2.2	3.8	1.9	0.0	1.8 (167)	0.0	0.0	0.0	1	1
SD BIOLINE Malaria Ag P.f/Pan <sup>i</sup>	05FK60	Standard Diagnostics Inc.	92.9	97.1	99.0	100.0	0.5 (394)	0.0	0.5	0.0	3.5 (199)	0.3	0.0	0.3	3	3
SD BIOLINE Malaria Ag <sup>j</sup>	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	83.8	0.0	100.0	100.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	3	3
Pf and Pv																
Advanced Quality™ One Step Malaria P.f/Pv Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	86.9	0.0	100.0	5.7	15.7 (395)	5.7	8.1 (197)	4.3	18.5	0.2	0.0	0.2	3	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	77.8	31.4	99.0	100.0	0.5	0.7	0.0	0.0	0.0	0.0	0.0	0.0	3	3
BIONOTE MALARIA P.f& P.v. Ag Rapid Test Kit	RG19-12	Bionote, Inc.	92.9	97.1	98.0	100.0	0.3	0.7	1.5 (197)	0.0	4.0	0.0	0.0	0.0	3	3
CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	90.0	90.0	100.0	100.0	0.3	0.6	0.0	0.0	0.5	0.0	0.0	0.0	2	2
CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	89.0	80.0	100.0	100.0	1.3	0.0	0.5	0.0	0.5	0.0	0.0	0.0	2	2

Table S1 (continued)

Product	Catalogue number	Manufacturer	Panel Detection Score <sup>a</sup>				False positive rates (%)						Total false positive rates <sup>b</sup> (%)		Invalid rate (%) (n=1204)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples		False positive <i>Plasmodium spp.</i> Infection <sup>i</sup>			
			Pf samples <sup>c</sup>	Pv samples <sup>d</sup>	Pf samples <sup>e</sup>	Pv samples <sup>f</sup>	Pf samples	Pv samples	False positive non-Pf infection <sup>g</sup>	False positive Pf infection <sup>h</sup>	False positive non-Pf infection <sup>g</sup>	False positive Pf infection <sup>h</sup>				
Core™ Malaria Pv/Pf diagnostics- Malaria (Pv/Pf) Cassette FalciVax Rapid Test for Malaria Pv/Pf (device) FirstSign™ – ParaView-2 (Pv + Pf) Card Test Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device Maleriscan® Malaria Pf/Pv OnSight™ – ParaQuick-2 (Pv/Pf) Malaria Test OnSite Malaria Pf/Pv Ag Rapid Test <sup>i</sup> SD BIOLINE Malaria Ag Pf/Pv Pf, Pv and Pan	MAL-190022	Core Diagnostics	98.0	60.0	100.0	97.1	0.3	0.0	0.0	0.0	4.0	0.1	3			
	KMVFC6002	SSA Diagnostics & Biotech Systems	91.0	45.0	99.0	100.0	0.3 (399)	0.6	0.0	0.0	2.0	0.1	2			
	50300025	Zephyr Biomedicals	92.0	45.0	100.0	100.0	0.0	1.3	0.0	0.0 (79)	4.5	0.2	2			
	2102CB-25	Unimed International, Inc.	48.1	0.0	98.7	85.0	1.0	3.8	N/A	5.0	0.0 (167)	0.0	1			
	MFV-124V	AZOG, Inc.	79.8	0.0	100.0	20.0	0.0	1.4	0.0	0.0	0.0 (199)	0.1	3			
	MAT-50	Bhat Bio-Tech India (P) Ltd	52.0	0.0	97.0	60.0	1.8 (399)	2.5	32.5	2.5 (79)	1.5 (199)	0.4	2			
	537-25-DB	Amgenix International, Inc.	92.0	37.5	100.0	100.0	0.5	1.9	0.0	0.0	3.5	0.1	2			
	R0112C	CTK Biotech, Inc.	84.9	97.1	100.0	100.0	5.3	0.0	6.1	0.0	28.0	0.0	3			
	05FK80	Standard Diagnostics, Inc.	96.0	95.0	100.0	100.0	0.0	0.0 (159)	0.0 (199)	0.0	3.5	0.2	2			
	Core™ Malaria Pan/Pv/Pf diagnostics MALARIA (Pan/Pv/Pf) Cassette FirstSign™ – ParaView-3 (Pan+Pv+Pf) Malaria Test Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device) Pan only Advantage Pan Malaria Card CareStart™ Malaria pLDH (PAN) Clearview® Malaria pLDH diagnostics MALARIA (Pan) Cassette First Response® Malaria Ag pLDH FirstSign™ – PanCheck (Pan) Malaria Test OnSight™ – PanScreen (Pan) Malaria Test Parabank™ Device – Rapid test for Malaria Pan <sup>i</sup> Pv only SD BIOLINE Malaria Ag Pv	MAL-190026	Core Diagnostics	92.9	11.4	99.0	94.3	0.3 (391)	0.0 (137)	0.0 (197)	1.4	3.5 (198)	1.0	3		
MPNFC10075		SSA Diagnostics & Biotech Systems	93.9	11.4	99.0	94.3	0.0 (389)	0.0 (139)	0.0 (196)	2.9 (69)	4.0 (199)	1.1	3			
2103 CB-25		Unimed International Inc.	89.0	45.0	100.0	100.0	0.0 (399)	2.5	0.0	0.0	24.5	0.1	2			
50320025		Zephyr Biomedicals	93.0	45.0	100.0	100.0	0.0 (396)	0.0 (159)	0.0 (199)	0.0	37.0 (198)	0.7	2			
IR013025		J. Mitra & Co. Pvt. Ltd.	72.2	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1.8	0.0	1			
G0111		Access Bio, Inc.	92.4	100.0	100.0	100.0	N/A	N/A	N/A	N/A	6.6	0.0	1			
70884025		Organics Ltd.	81.8	85.7	99.0	100.0	N/A	N/A	N/A	N/A	13.5	0.5	3			
MPNWBCT0073		SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	N/A	N/A	N/A	N/A	0.0	0.3	3			
112FRC30		Premier Medical Corporation Ltd.	31.0	92.5	98.0	100.0	N/A	N/A	N/A	N/A	0.0	0.0	2			
2104 CB-25		Unimed International Inc.	25.0	82.5	87.0	100.0	N/A	N/A	N/A	N/A	2.5	0.2	2			
OnSight™ – PanScreen (Pan) Malaria Test Parabank™ Device – Rapid test for Malaria Pan <sup>i</sup> Pv only SD BIOLINE Malaria Ag Pv	539-25-DB	Amgenix International, Inc.	22.0	77.5	96.0	100.0	N/A	N/A	N/A	N/A	2.5	0.2	2			
	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	N/A	N/A	N/A	N/A	0.5	0.2	3			
05FK70	Standard Diagnostics, Inc.	N/A	92.5	N/A	N/A	100.0	0.3	N/A	1.0	N/A	1.0	0.0	2			

<sup>a</sup> For combination tests, Pan or Pv line, only, positive indicates a false positive *P. falciparum* infection (Round 1, n=158, Round 2, n=200; Round 3, n=198)

<sup>b</sup> Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=40; Round 2, n=80, Round 3, n=70)

<sup>c</sup> Pf: *Plasmodium falciparum*    Pv: *Plasmodium vivax*    pan: *Plasmodium* species

<sup>d</sup> A sample is considered detected only if all RDts from both lots read by the first technician, at minimum specified reading time, are positive

<sup>e</sup> The total number of times a positive result for malaria was generated when it was used

Pf: *Plasmodium falciparum* Pv: *Plasmodium vivax* pan: *Plasmodium* species<sup>a</sup> A sample is considered detected only if all RDIs from both lots read by the first technician, at minimum specified reading time, are positive<sup>b</sup> The total number of times a positive result for malaria was generated when it should not have been<sup>c</sup> Round 1, n=79; Round 2, n=100; Round 3, n=99<sup>d</sup> Round 1, n=20; Round 2, n=40; Round 3, n=35<sup>e</sup> For combination tests, Pan or Pv line, only, positive indicates a false positive *P. falciparum* infection (Round 1 n=316; Round 2, n=400; Round 3, n=396)<sup>f</sup> Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=80; Round 2, n=160; Round 3, n=140)<sup>g</sup> For combination tests, Pan or Pv line, only, positive indicates a false positive *P. falciparum* infection (Round 1, n=158; Round 2, n=200; Round 3, n=198)<sup>h</sup> Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=40; Round 2, n=80; Round 3, n=70)<sup>i</sup> Round 1, n=168; Round 2, n=200; Round 3, n=200<sup>j</sup> Product resubmission results from most recent round of testing replace previous results. Refer to Table S3.<sup>k</sup> PDS presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH). *P. falciparum* PDS based on individual test lines was : pf-pLDH (17.2% at 200p/µl; 97% at 2000p/µl) and pf-HRP2 (87.9% at 200p/µl; 100% at 2000p/µl)

Table S2: Malaria RDT Rounds 1–3 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/μl). Positivity rate at baseline, and after 60 days incubation at 35°C and 45°C

Product	Catalogue number	Manufacturer	Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pan line)			Round	
			200 parasites/μl			2000 parasites/μl			200 parasites/μl				
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C		
			Number of tests positive			Number of tests positive			Number of tests positive				
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined				
Pf only													
Advanced Quality™ One Step Malaria Pf Test <sup>a</sup>	ITP11002TC40	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Advanced Quality™ Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	80.0	95.0	90.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
Advantage Pf. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	95.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	86.7	100.0	90.0	80.0	N/A	N/A	N/A	N/A	3
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	2
Clearview® Malaria Pf: <sup>a</sup>	V801	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	96.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
diagnostics- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	95.0	70.0	55.0	95.0	95.0	95.0	N/A	N/A	N/A	N/A	2
diagnostics- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	2
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	20.0	15.0	0.0	100.0	90.0	95.0	N/A	N/A	N/A	N/A	1
Hexagon Malaria	58051	Human GmbH	50.0	35.0	60.0	95.0	100.0	100.0	N/A	N/A	N/A	N/A	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	2
ICT Diagnostics Malaria Pf: <sup>a</sup>	ML01	ICT Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Immunorapid Malaria Falciparum	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
Malaria Plasmodium falciparum Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	96.7	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
One Step Malaria P.F Test (cassette) <sup>a</sup>	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	63.3	0.0	0.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
One Step Malaria P.F Test <sup>a</sup>	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	93.3	90.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
OnSite™ – Malaria Pf Test	511-25-DB	Amgenix International, Inc.	100.0	95.0	90.0	100.0	100.0	65.0	N/A	N/A	N/A	N/A	2
OnSite Pf Ag Rapid Test <sup>a</sup>	R0114C	CTK Biotech, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Paracheck® Pf Device- Rapid test for <i>P. falciparum</i> Malaria Ver. 3 <sup>a</sup>	30301025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Paracheck® Pf Dipstick- Rapid test for <i>P. falciparum</i> Malaria Ver. 3 <sup>a</sup>	30302025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
ParaHIT® - f (Device) <sup>b</sup>	551C102-50	Span Diagnostics Ltd.	100.0	96.7	100.0	100.0	100.0	90.0	N/A	N/A	N/A	N/A	3
ParaHIT® - f (Dipstick) <sup>b</sup>	551C101-50	Span Diagnostics Ltd.	100.0	100.0	56.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
SD BIOLINE Malaria Ag Pf. (HRP2/pLDH) <sup>b</sup>	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	1
Pf and Pan													
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	100.0	80.0	90.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	3
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	55.0	95.0	100.0	95.0	55.0	45.0	40.0	100.0	1
BinaX Now Malaria Test	IN660050	Inverness Medical Innovations, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	5.0	0.0	0.0	95.0	1
BIONOTE MALARIA P.f.f.t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	3
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio Inc	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131	Access Bio, Inc.	100.0	95.0	100.0	100.0	100.0	100.0	100.0	95.0	100.0	100.0	1
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3

Table S2 (continued)

Product	Catalogue number	Manufacturer	Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pan line)			Round	
			200 parasites/μl			2000 parasites/μl			200 parasites/μl				
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C		
			Number of tests positive			Number of tests positive			Number of tests positive				
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined				
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	100.0	100.0	93.3	100.0	100.0	100.0	100.0	93.3	100.0	100.0	3
Clearview® Malaria Combo <sup>a</sup>	VB11	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	20.0	3
Clearview® Malaria Dual Test Device <sup>a</sup>	VB20	Vision Biotech (Pty) Ltd	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	50.0	3
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	90.0	3
First Response® Malaria pLDH/HRP2 Combo Test <sup>a</sup>	I16FRC30	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	85.0	55.0	100.0	100.0	2
FirstSign™ – ParaView (Pan+Pf) Malaria Test	2101 CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	95.0	40.0	100.0	100.0	2
Hexagon Malaria Kombi	58024	Human GmbH	65.0	55.0	50.0	100.0	85.0	95.0	0.0	0.0	0.0	0.0	1
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	35.0	0.0	5.0	100.0	100.0	100.0	0.0	0.0	0.0	35.0	2
HiSens Malaria Ag P.f/P.v (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	2
ICT Diagnostics Malaria Combo <sup>a</sup>	ML02	ICT Diagnostics	100.0	100.0	96.7	100.0	100.0	90.0	0.0	0.0	0.0	90.0	3
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	100.0	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	100.0	3
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	50.0	3
Immunoquick Malaria +4	0506_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	1
Malaria P.f/Vivax	172110P-25	Diagnostics Automation/Cortez Diagnostics, Inc.	65.0	15.0	20.0	65.0	45.0	5.0	0.0	0.0	0.0	0.0	1
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	60.0	33.3	23.3	100.0	100.0	90.0	13.3	53.3	40.0	10.0	3
Malaria pf (HRP II) / (PAN–pLDH) Antigen Detection Test Device <sup>a</sup>	MFV- 124R	AZOG, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	3
Malaria pf (pLDH) / PAN–pLDH Test Device	MFV-124	AZOG, Inc.	3.3	0.0	0.0	40.0	10.0	0.0	0.0	0.0	0.0	0.0	3
Malascan™ Device – Rapid test for Malaria P.f/Pan <sup>a</sup>	50402025	Zephyr Biomedical Systems	96.7	100.0	96.7	100.0	100.0	100.0	0.0	0.0	6.7	100.0	3
NanoSign Malaria P.f/Pan Ag	RMAP10	Bioland, Ltd	100.0	100.0	100.0	100.0	100.0	90.0	0.0	0.0	0.0	0.0	3
NanoSign Malaria P.f/Pv Ag	RMAD10	Bioland, Ltd	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	3
One Step Malaria Antigen Strip	820-1	IND Diagnostic Inc.	15.0	0.0	0.0	65.0	50.0	0.0	15.0	0.0	0.0	65.0	1
One Step Malaria P.f/Pan Test <sup>a</sup>	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	46.7	13.3	26.7	100.0	100.0	100.0	0.0	36.7	73.3	70.0	3
OnSite™ – ParaQuick (Pan, Pf) Test	536-25DB	Amgenix International, Inc.	100.0	90.0	60.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	1
OnSite P.f/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	3.3	66.7	83.3	100.0	3
OptiMAL-IT	710024	Diamed – A Division of Bio-Rad	0.0	0.0	0.0	100.0	90.0	0.0	0.0	0.0	0.0	100.0	3
ParaHiT® total (dipstick)	55(C201-10	Span Diagnostics Ltd	55.0	85.0	55.0	100.0	100.0	95.0	10.0	0.0	0.0	50.0	2
Parahit-Total Device Rapid test for <i>P. falciparum</i> and Pan malarial species	25989	Span Diagnostics Ltd.	65.0	75.0	25.0	95.0	100.0	100.0	5.0	0.0	0.0	0.0	1
Parascreen™ Device – Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	3
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.	15.0	0.0	0.0	65.0	50.0	0.0	15.0	0.0	0.0	65.0	1
SD BIOLINE Malaria Ag P.f/Pan <sup>a</sup>	05FK60	Standard Diagnostics Inc.	100.0	96.7	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	3
SD BIOLINE Malaria Ag <sup>a</sup>	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	100.0	80.0	90.0	0.0	0.0	0.0	80.0	3
Surestep™ Easy Malaria P.f/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	3
Pf and Pv													
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	IntTec Products, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	100.0	96.7	96.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
BIONOTE MALARIA P.f & P.v Ag Rapid Test Kit	RG19-12	Bionote, Inc.	100.0	96.7	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	3
CareStart™ Malaria HRP2/PLDH (P.f/P.v) COMBO	G0161	Access Bio, Inc.	100.0	100.0	95.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	2



Product	Catalogue number	Manufacturer	Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pf line)			Percent positive test results for <i>P. falciparum</i> (Pan line)			Round
			200 parasites/μl			2000 parasites/μl			200 parasites/μl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
CareStart™ Malaria HRP2/pLDH (Pf)/VOM) COMBO	G0171	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	2
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	3
diagnostics- Malaria (Pv/Pf) Cassette	KMVC6002	SSA Diagnostics & Biotech Systems	100.0	95.0	100.0	100.0	100.0	95.0	N/A	N/A	N/A	2
FalciVax Rapid Test for Malaria Pv/Pf (device)	50300025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	2
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	95.0	70.0	0.0	100.0	95.0	75.0	N/A	N/A	N/A	1
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	N/A	N/A	N/A	3
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	100.0	60.0	30.0	100.0	90.0	95.0	N/A	N/A	N/A	2
OnSight™ – ParaQuick-2 (Pv/Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	100.0	100.0	100.0	100.0	100.0	85.0	N/A	N/A	N/A	2
OnSite Malaria Pf/Pv Ag Rapid Test <sup>a</sup>	R0112C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	3
SD BIOLINE Malaria Ag Pf/Pv	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	N/A	N/A	N/A	2
Pf, Pv and Pan												
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	100.0	100.0	100.0	100.0	90.0	100.0	0.0	0.0	0.0	3
diagnostics MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	96.7	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	3
FirstSign™ – ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	60.0	50.0	15.0	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	25.0	30.0	2
Pan Only												
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	50.0	65.0	70.0	1
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	100.0	100.0	90.0	1
Clearview® Malaria pLDH <sup>a</sup>	70884025	Orgenics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	96.7	93.3	100.0	3
diagnostics MALARIA (Pan) Cassette	MPNVBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A	0.0	0.0	0.0	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	50.0	80.0	55.0	2
FirstSign™ – PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	N/A	N/A	N/A	N/A	N/A	N/A	25.0	5.0	10.0	2
OnSight™ – PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	5.0	35.0	15.0	2
Parabank™ Device – Rapid test for Malaria Pan <sup>a</sup>	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	0.0	0.0	0.0	3
Pv only												
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2

Pf: *Plasmodium falciparum* Pv: *Plasmodium vivax* pan: *Plasmodium* species

<sup>a</sup> Product resubmission, results from most recent round of testing replace previous results. Refer to Table S3.

<sup>b</sup> Results presented in the table are based on stability of a pf test line (either pf-HRP2 or pf-pLDH). Results based on stability of individual test lines on 200p/μl and 2000p/μl samples were, respectively: pf-pLDH (0%; 33.3% detected at baseline and 0%; 33.3% detected post 60 d incubation at 35°C, 45°C) and pf-HRP2 (100%; 100% at baseline and 100%; 100% post 60 d incubation at 35°C, 45°C)

Table S3: Product Resubmissions: WHO Malaria RDT Product Testing – Rounds 1–3

Manufacturer	Initial Testing			Subsequent Testing		
	Round	Product Name	Catalogue No	Round	Product Name	Catalogue No
AZOG, Inc.	1	Malaria Pf (HRPII)/pv-LDH Antigen Detection Test Device <sup>a</sup>	MFV-124R	3	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R
Blue Cross Bio-Medical (Beijing) Co., Ltd.	2	One Step Malaria Pf Test (cassette)	522352	3	One Step Malaria Pf Test (cassette)	522352
CTK Biotech, Inc.	2	Onsite Pf Ag Rapid Test	R0114C	3	OnSite Pf Ag Rapid Test	R0114C
	2	Onsite Pf/Pan Ag Rapid Test	R0113C	3	OnSite Pf/Pan Malaria Ag Rapid Test	R0113C
	2	Onsite Pf/Pv Ag Rapid Test	R0112C	3	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C
	1	OptiMAL-IT	710024	3	OptiMAL-IT	710024
Guangzhou Wondfo Biotech Co. Ltd.	1	Wondfo One Step Malaria Pf/Pan Whole Blood Test	W56-C (4.0mm)	3	One Step Malaria Pf./Pan Whole Blood Test	W56-C
	2	One Step Malaria Pf Test <sup>b</sup>	W37-C (4.0mm)	3	One Step Malaria Pf Test	W37-C
ICT Diagnostics	1	ICT Malaria Combo Cassette Test	ML02	3	ICT Diagnostics Malaria Combo	ML02
	1	ICT Malaria Pf Cassette Test	ML01	3	ICT Diagnostics Malaria P.f	ML01
Intec Products, Inc.	1	ADVANCED QUALITY™ One Step Malaria (p.f.) Test (whole blood)	ITP11002TC40	3	Advanced Quality™ One Step Malaria Pf Test	ITP11002 TC40
Orchid Biomedical Systems	1	Paracheck Pf Rapid test for Pfalciparum Malaria (Device)	30301025	3	Paracheck® Pf Device – Rapid test for <i>P. falciparum</i> Malaria (Ver.3)	30301025
	1	Paracheck Pf Rapid test for Pfalciparum Malaria (Dipstick)	30302025	3	Paracheck® Pf Dipstick – Rapid test for <i>P. falciparum</i> Malaria (Ver.3)	30302025
Premier Medical Corporation Ltd.	1	First Response Malaria Ag Combo (pLDH/HRP2)	116FRC30	2	First Response® Malaria Ag Combo (pLDH/HRP2)	116FRC30
Span Diagnostics Ltd.	1	Parahit-f TEST DEVICE FOR FALCIPARUM MALARIA	25975	3	ParahIT® – f (Device)	551C102-10
	1	Parahit-f DIPSTICK FOR FALCIPARUM MALARIA	25977	3	ParahIT® – f (Dipstick)	551C101-10
Standard Diagnostics Inc. (Now Alere Healthcare (Pty) Ltd)	1	SD BIOLINE Malaria Ag	05FK40-02-5 <sup>d</sup>	3	SD BIOLINE Malaria Ag	05FK40
	1	SD BIOLINE Malaria Ag Pf/Pan	05FK60-02-3 <sup>d</sup>	3	SD BIOLINE Malaria Ag P.f/Pan	05FK60
Vision Biotech (Pty) Ltd (Now Alere Healthcare (Pty) Ltd)	1	Malaria Rapid Combo	VB011	3	Clearview® Malaria Combo	VB11 <sup>e</sup>
	1	Malaria Rapid Pf	VB01	3	Clearview® Malaria Pf	VB01
Zephyr Biomedical Systems	1	Malaria Rapid Dual	VB020	3	Clearview® Malaria Dual Test Device	VB20 <sup>e</sup>
	1	Malascan Rapid Test for Malaria Pf/Pan (Device)	50402025	3	Malascan™ Device – Rapid test for Malaria Pf/Pan	50402025
	1	Parabank Rapid Test for Malaria Pan (Device)	50301025	3	Parabank™ Device – Rapid test for Malaria Pan	50301025
	1	Parascreen Rapid Test for Malaria Pan/Pf (Device)	50310025	3	Parascreen™ Device – Rapid test for Malaria Pan/Pf	50310025

<sup>a</sup> Round 1 product name error : published – Malaria Pf (HRPII)/pv-LDH Antigen Detection Test Device Code ; corrected product name: Malaria Pf (HRPII)/PAN-LDH Antigen Detection Test Device Code. No change in product code.

<sup>b</sup> In Round 2, product did not pass Phase 1, therefore results do not feature in Summary tables.

<sup>c</sup> Error in WHO Malaria RDT Product Testing: Round 1 report: product code (116FRC30) should have been (116FRC30), as in Round 2

<sup>d</sup> 02-05/02-03 suffix refers to version of the package inserts

<sup>e</sup> New company acquisition (Alere™) –hence name changes/product codes. Manufacturer confirmed compliance with product definition.







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