Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: Round 4 (2012)

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FIND foundation for innovative new diagnostics
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ABBREVIATIONS

ACT	Artemisinin-based combination therapy
AMI	Army Malaria Institute
CDC	United States Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
DFID	UK Department for Overseas Development
FIND	Foundation for Innovative New Diagnostics
FP	False-positive
HRP2	Histidine-rich protein 2
HTD	Hospital for Tropical Diseases
ISO	International Organization for Standardization
PCR	Polymerase chain reaction
PDS	Panel detection score
pLDH	*Plasmodium* lactate dehydrogenase
Pf	*Plasmodium falciparum*
Pv	*Plasmodium vivax*
Pvom	*Plasmodium vivax, ovale, malariae*
PR	*Positivity rate*
p/µL	Parasites per microlitre
QA	Quality assurance
QC	Quality control
QMS	Quality management systems
RDT	Rapid diagnostic test (for the purposes of this report, this refers to immunochromatographic lateral flow devices for the detection of malaria parasite antigens)
SOP	Standard Operating Procedure
TDR	Special Programme for Research and Training in Tropical Diseases sponsored by UNICEF, UNDP, World Bank and WHO
UN	United Nations
USA	United States of America
USAID	United States Agency for International Development
WPRO	Western Pacific Regional Office
WHO	World Health Organization

1. SUMMARY PERFORMANCE OF MALARIA RDTS: WHO PRODUCT TESTING: ROUNDS 1–4

1.1. Introduction

The World Health Organization estimates that half the world's population is at risk of malaria, with an estimated 216 million people (range 149–274 million) developing clinical malaria in 2010 (81% in Africa), and 655,000 deaths (range 537,000–907,000) due to malaria (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 confirmed, resulting in over-use of anti-malarial drugs and poor disease monitoring[1].

WHO recommends that malaria case management be based on parasite-based diagnosis in all cases[2]. 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 by providing 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. Currently, these data are guiding procurement decisions which are in turn shifting markets towards better-performing tests[1] and helping to drive overall improvement in the quality of manufacturing. The results of WHO Malaria RDT Product Testing have been published annually since 2009 and form the basis of procurement criteria of WHO, other UN agencies, the Global Fund and national governments.

This Summary presents an overview of the results of the first through fourth rounds of WHO Malaria RDT Product Testing and is published in conjunction with the release of the full report on Round 4. The results of the four rounds of testing should be considered as a single data set. 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[3]. All companies manufacturing under ISO 13485:2003 Quality System Standard were invited to submit a limited number of products (2–3) 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, 50 and 48 products from 13, 23 and 27 manufacturers were evaluated in Round 2, 3 and 4, respectively. Many manufacturers have decided to voluntarily re-submit products to one or more rounds of testing, including 1, 23 and 13 resubmissions in Round 2, 3 and 4, respectively (Table S3). Of these 168 total products, 164 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 164 fully evaluated products, 21 have been evaluated twice, and 8 have been evaluated three times between Rounds 1-4. Of the 128 unique products tested by the programme, 35 detect *P. falciparum* alone, 83 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific (Pv, Pvom), 9 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[4] have been re-submitted in subsequent rounds of testing, the latter results replace those published from the earlier round. Thus, the performance of many tests in the results below differ from those published in the Rounds 1–3 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.

[1] *World Malaria Report 2011.* Geneva, World Health Organization, 2011

[2] *Guidelines for the Treatment of Malaria, Second Edition.* Geneva, World Health Organization, 2010 (ISBN9789241547925)

[3] See full reports of Rounds 1–4 for full list of collaborating partners.

[4] *Informal Consultation on Laboratory Methods for Quality Assurance of Malaria Rapid Diagnostic Tests.* 20-22 July 2004. Manila. WHO Regional Office for the Western Pacific. 2004. (RS/2004/GE/26(PHL)

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 fifth round of product testing will begin in January 2013.

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[1]. For the purposes of this report, the main measure of performance is the 'panel detection score (PDS)'[2]; 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 a RDT to detect malaria is highly dependent on the local conditions, including parasite density in the target population. Sensitivity of a test will therefore vary among populations with differing levels of transmission, as their different levels of immunity 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 among 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[3]. 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,[4] and at *www.wpro.who.int/sites/rdt*. WHO provides guidance on the procurement and implementation of malaria RDTs[5,6] . Furthermore, 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.[7]

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1 *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)

2 Termed 'Detection Rate' in the full report of Round 1, published in 2009. See the Round 4 report for a full explanation of the panel detection score (PDS).

3 Gamboa, D., M. F. Ho, et al. *A large proportion of P. falciparum isolates in the Amazon region of Peru lack pfhrp2 and pfhrp3: implications for malaria rapid diagnostic tests. PLoS One*, 2010: 5(1): e8091.

4 *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;
Malaria Rapid Diagnostic Test Performance : Results of WHO product testing of malaria RDTs: Round 3 (2010-11). Geneva, World Health Organization, 2011. ISBN 978 92 4 150256 6.

5 *Good practices for selecting and procuring rapid diagnostic tests for malaria.* Geneva, World Health Organization , 2011 (ISBN 978 92 4 150112 5)

6 *Universal Access to Malaria Diagnostic Testing: An operational manual.* Geneva, World Health Organization, 2011 (ISBN 978 92 4 150209)

7 Malaria RDT Interactive Guide : http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp

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, the gains noted in the performance of products re-submitted to Round 3 were seen again in Round 4 for several products (Table S3), indicating product improvement by the manufacturers. Furthermore, in Round 4 the proportion of tests achieving a PDS (>75%) at 200 parasites/µl is comparable to Round 3 for *P. falciparum* at 73.9% and for *P. vivax*, the proportion is 47.2 %, representing an improvement over Rounds 1 and 3 combined (36.7%).

Several RDTs from the four 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 among 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. In Round 4, both tests targeting pf-pLDH for detection of *P. falciparum* infection did not pass Phase 1. Thus, the range of choice for well-performing pLDH based *P. falciparum* tests remains limited, as it does for pan-only specific tests.

Test performance sometimes 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 of *P. falciparum* isolates to manufacturers to assist in this process and is planning to transition to malaria recombinant antigens panels by the end of 2014.

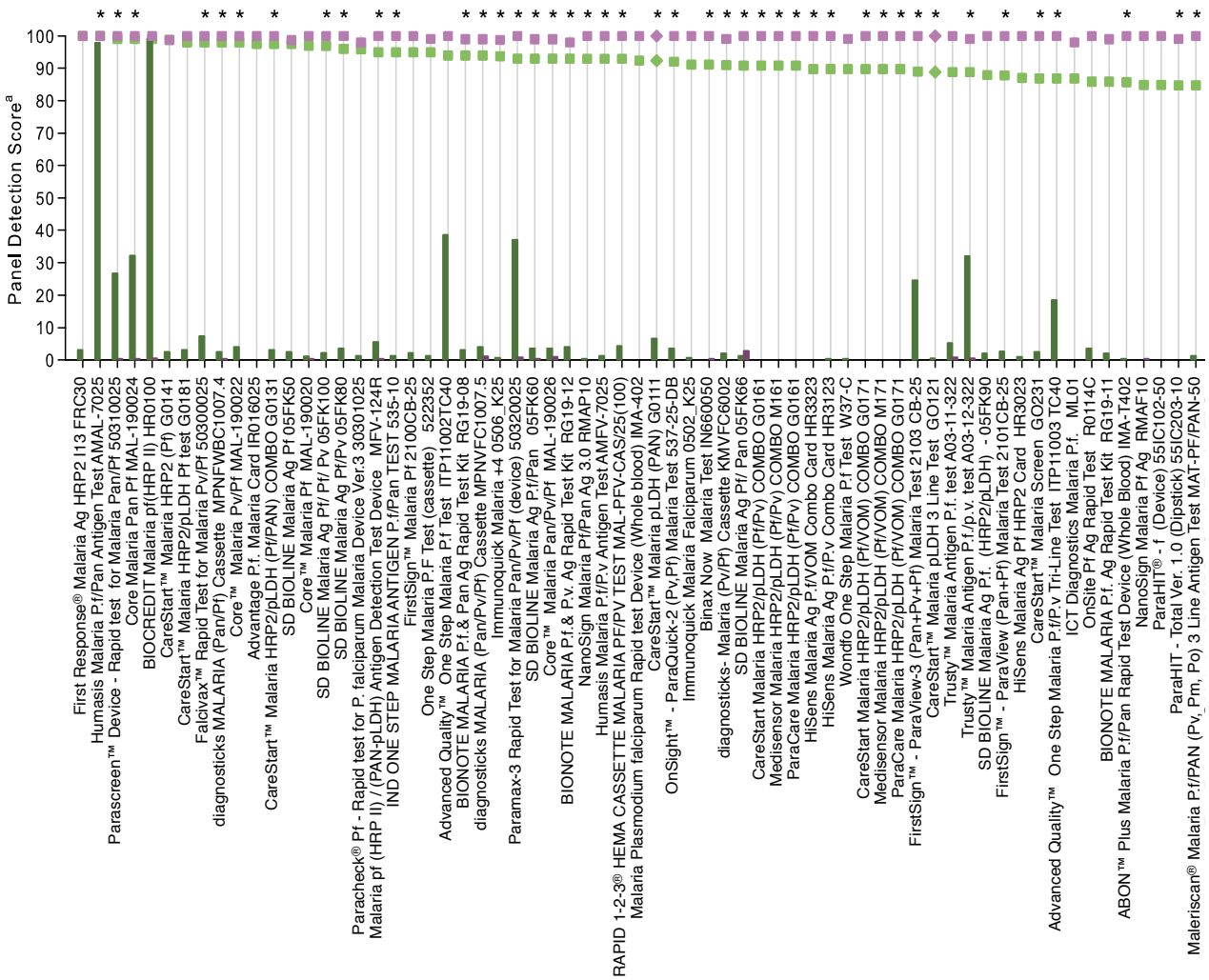
1.5. Use of these results

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 settings 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[1]. 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*'[2].

[1] 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 contacting *Malaria_rdt@who.int* and *info@finddiagnostics.org*.

[2] *Good Practices for selecting and procuring rapid diagnostic tests for malaria*, Geneva, World Health Organization, 2011 (ISBN 9789241501125)

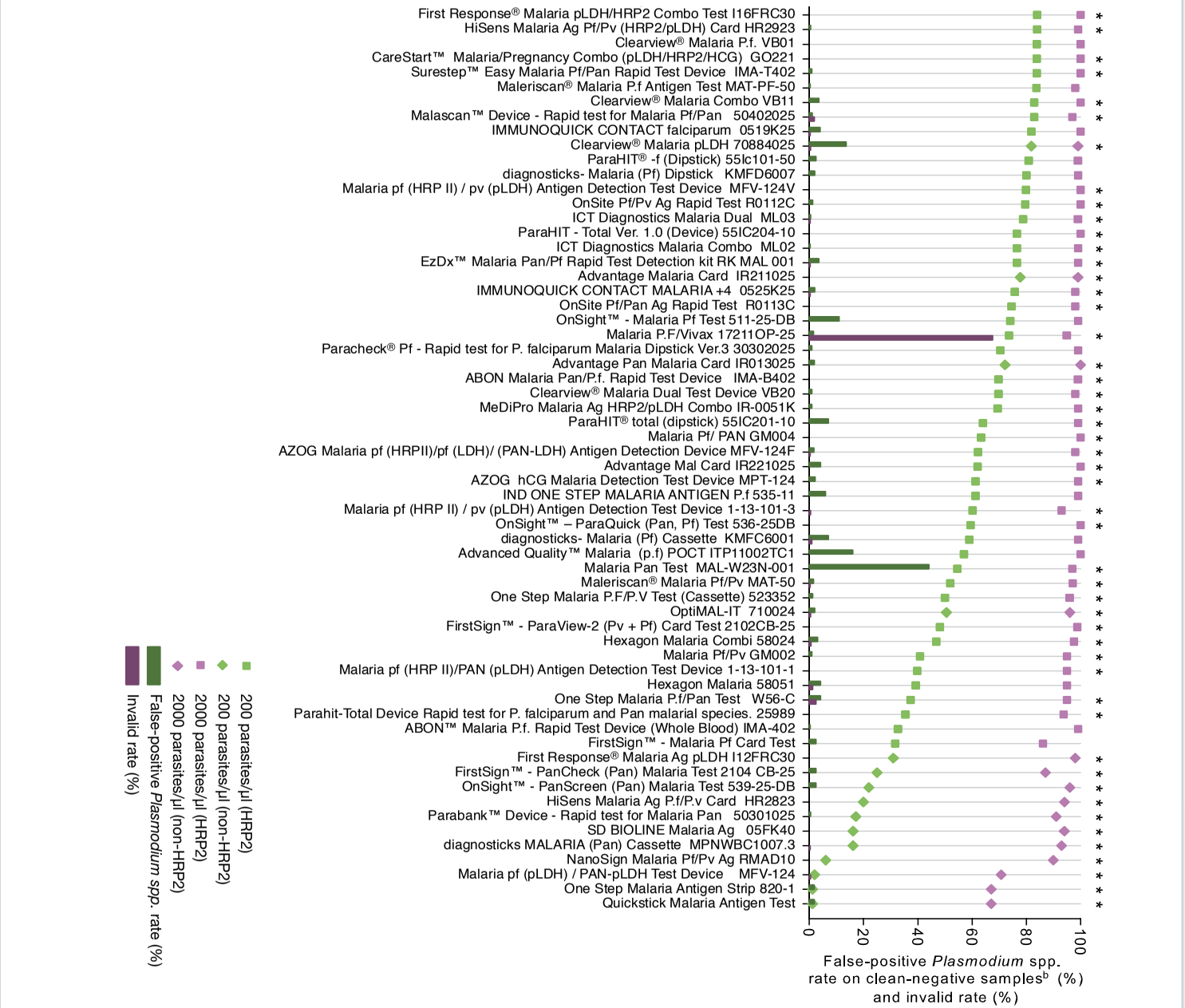
Figure S1: Malaria RDT performance in Phase 2 of Rounds 1–4 against wild type (clinical) samples containing *P. falciparum* at low (200) and high (2000–5000) parasite densities (parasites/µl) and clean-negative samples



[a] Panel detection score - 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] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

* Indicates tests that also detect other non-*P. falciparum* parasites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HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card HR2923
Clearview® Malaria P.f. VB01
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) GO221
Surestep™ Easy Malaria Pf/Pan Rapid Test Device IMA-T402
Maleriscan® Malaria P.f Antigen Test MAT-PF-50
Clearview® Malaria Combo VB11
Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
IMMUNOQUICK CONTACT falciparum 0519K25
Clearview® Malaria pLDH 70884025
ParaHIT® -f (Dipstick) 55Ic101-50
diagnosticks- Malaria (Pf) Dipstick KMFD6007
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
OnSite Pf/Pv Ag Rapid Test R0112C
ICT Diagnostics Malaria Dual ML03
ParaHIT - Total Ver. 1.0 (Device) 55IC204-10
ICT Diagnostics Malaria Combo ML02
EzDx™ Malaria Pan/Pf Rapid Test Detection kit RK MAL 001
Advantage Malaria Card IR211025
IMMUNOQUICK CONTACT MALARIA +4 0525K25
OnSite Pf/Pan Ag Rapid Test R0113C
OnSight™ - Malaria Pf Test 511-25-DB
Malaria P.F/Vivax 17211OP-25
Paracheck® Pf - Rapid test for P. falciparum Malaria Dipstick Ver.3 30302025
Advantage Pan Malaria Card IR013025
ABON Malaria Pan/P.f. Rapid Test Device IMA-B402
Clearview® Malaria Dual Test Device VB20
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
ParaHIT® total (dipstick) 55IC201-10
Malaria Pf/ PAN GM004
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
Advantage Mal Card IR221025
AZOG hCG Malaria Detection Test Device MPT-124
IND ONE STEP MALARIA ANTIGEN P.f 535-11
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
OnSight™ – ParaQuick (Pan, Pf) Test 536-25DB
diagnosticks- Malaria (Pf) Cassette KMFC6001
Advanced Quality™ Malaria (p.f) POCT ITP11002TC1
Malaria Pan Test MAL-W23N-001
Maleriscan® Malaria Pf/Pv MAT-50
One Step Malaria P.F/P.V Test (Cassette) 523352
OptiMAL-IT 710024
FirstSign™ - ParaView-2 (Pv + Pf) Card Test 2102CB-25
Hexagon Malaria Combi 58024
Malaria Pf/Pv GM002
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
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One Step Malaria P.f/Pan Test W56-C
Parahit-Total Device Rapid test for P. falciparum and Pan malarial species. 25989
ABON™ Malaria P.f. Rapid Test Device (Whole Blood) IMA-402
FirstSign™ - Malaria Pf Card Test
First Response® Malaria Ag pLDH I12FRC30
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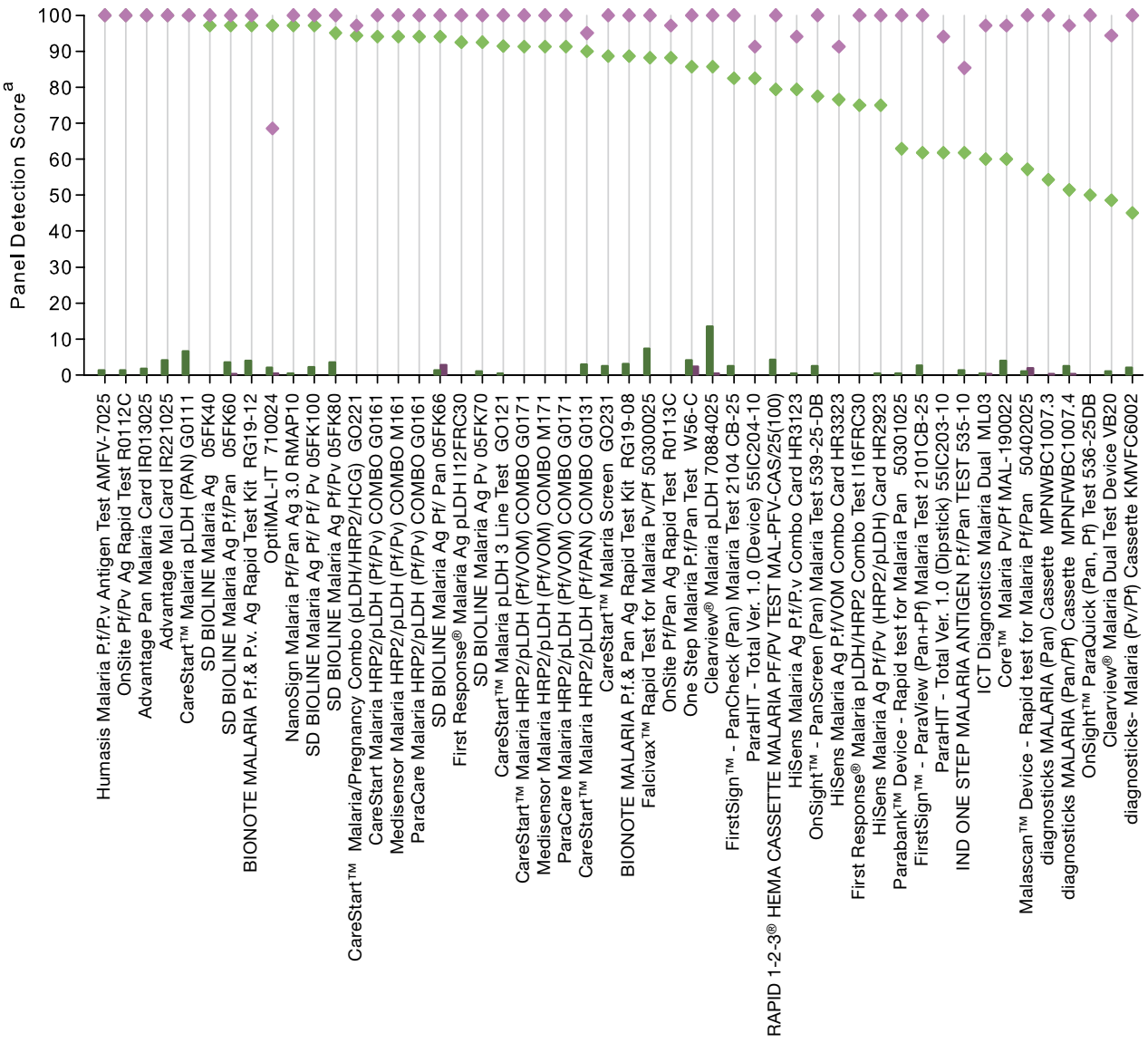
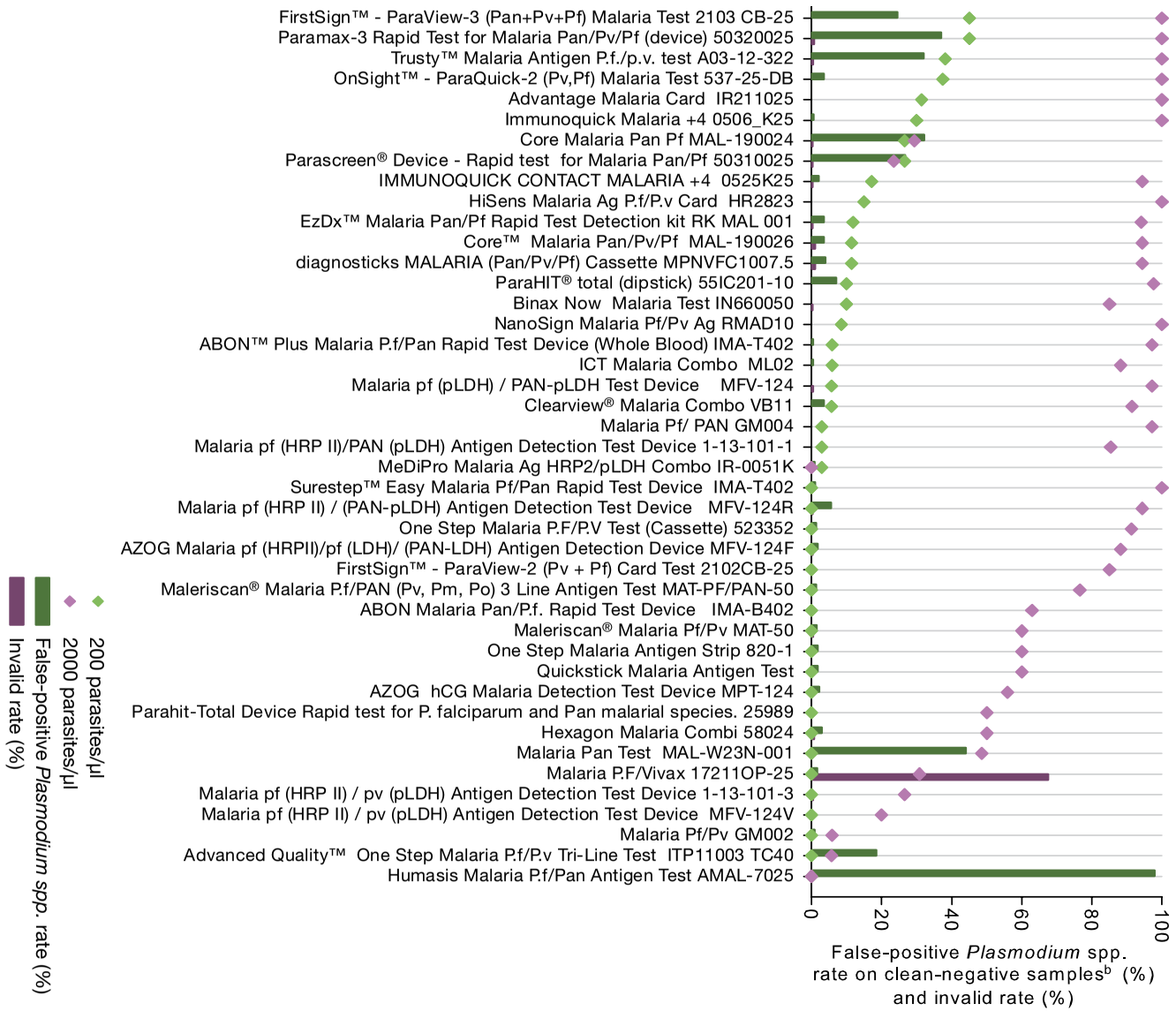
OnSight™ - PanScreen (Pan) Malaria Test 539-25-DB
HiSens Malaria Ag P.f/P.v Card HR2823
Parabank™ Device - Rapid test for Malaria Pan 50301025
SD BIOLINE Malaria Ag 05FK40
diagnosticks MALARIA (Pan) Cassette MPNWBC1007.3
NanoSign Malaria Pf/Pv Ag RMAD10
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
One Step Malaria Antigen Strip 820-1
Quickstick Malaria Antigen Test
0
20
40
60
80
100
False-positive *Plasmodium* spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µl (HRP2)
200 parasites/µl (non-HRP2)
2000 parasites/µl (HRP2)
2000 parasites/µl (non-HRP2)
False-positive *Plasmodium spp.* rate (%)
Invalid rate (%)

Figure S2: Malaria RDT performance in Phase 2 of Rounds 1–4 against wild type (clinical) samples containing *P. vivax* at low (200) and high (2000–5000) parasite densities (parasites/µl)) and clean-negative samples



[a] Panel detection score - 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] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.


FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test 2103 CB-25
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device) 50320025
Trusty™ Malaria Antigen P.f./p.v. test A03-12-322
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test 537-25-DB
Advantage Malaria Card IR211025
Immunoquick Malaria +4 0506_K25
Core Malaria Pan Pf MAL-190024
Parascreen® Device - Rapid test for Malaria Pan/Pf 50310025
IMMUNOQUICK CONTACT MALARIA +4 0525K25
HiSens Malaria Ag P.f/P.v Card HR2823
EzDx™ Malaria Pan/Pf Rapid Test Detection kit RK MAL 001
Core™ Malaria Pan/Pv/Pf MAL-190026
diagnosticks MALARIA (Pan/Pv/Pf) Cassette MPNVFC1007.5
ParaHIT® total (dipstick) 55IC201-10
Binax Now Malaria Test IN660050
NanoSign Malaria Pf/Pv Ag RMAD10
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) IMA-T402
ICT Malaria Combo ML02
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
Clearview® Malaria Combo VB11
Malaria Pf/ PAN GM004
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
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Maleriscan® Malaria Pf/Pv MAT-50
One Step Malaria Antigen Strip 820-1
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Malaria Pf/Pv GM002
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test ITP11003 TC40
Humasis Malaria P.f/Pan Antigen Test AMAL-7025
0
20
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60
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100
False-positive *Plasmodium* spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µl
2000 parasites/µl
False-positive *Plasmodium spp.* rate (%)
Invalid rate (%)

Table S1: Malaria RDT Phase 2 performance in Rounds 1–4 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[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%) (n=1192)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non Pf infection[e]	False-positive Pf infection[f]	False-positive non Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
Pf only													
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	4
Advanced Quality™ One Step Malaria P.f Test[j]	ITP11002TC40	InTec Products, Inc.	93.9	NA	100.0	NA	NA	40.0	NA	35.7	38.5	0.1	3
Advanced Quality™Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	57.0	NA	100.0	NA	NA	12.5	NA	17.5	16.1	0.0	1
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	97.5	NA	100.0	NA	NA	1.3	NA	2.5	0.0	0.0	1
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	99.0	NA	100.0	NA	NA	97.1	NA	95.59	99.1 (231)	0.5	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	85.9	NA	99.0	NA	NA	0.0	NA	1.4	2.0	0.1	3
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	98.7	NA	98.7	NA	NA	5.0	NA	7.5	2.4	0.0	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	NA	100.0	NA	NA	0.6	NA	1.3	3.0	0.0	2
Clearview® Malaria P.f.[j]	VB01	Vision Biotech (Pty) Ltd	83.8	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0 (198)	0.3	3
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	59.0	NA	99.0	NA	NA	1.9	NA	2.6 (77)	7.0	0.9	2
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	NA	99.0	NA	NA	2.5	NA	3.8	2.0	0.0	2
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.	100.0	NA	100.0	NA	NA	0.0	NA	0.0	3.0	0.0	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	31.7	NA	86.1	NA	NA	12.5	NA	15.0	2.4 (166)	0.0	1
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.47	2.2 (231)	0.2	4
Hexagon Malaria	58051	Human GmbH	39.2	NA	94.9	NA	NA	7.9 (76)	NA	2.5	4.2 (167)	1.2	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	87.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.1	2
ICT Diagnostics Malaria P.f.[j]	ML01	ICT Diagnostics	86.9	NA	98.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	NA	100.0	NA	NA	3.6 (139)	NA	1.4	4.0 (199)	0.3	3
Immunoquick Malaria Falciparum	0502_K25	Biosynex	91.1	NA	100.0	NA	NA	0.0	NA	0.0	0.6	0.0	1
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	61.2	NA	99.0	NA	NA	2.2	NA	14.71	6	0.1	4
Malaria Plasmodium falciparum Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	92.4	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	1
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	98.0	NA	NA	1.5	NA	0.0	0.4	0.2	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.3	3
One Step Malaria P.F Test (Cassette)[j]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0.0	NA	1.47	1.3	0.0	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	NA	99.0	NA	NA	8.1	NA	2.5	11.0	0.0	2
OnSite Pf Ag Rapid Test[j]	R0114C	CTK Biotech, Inc.	85.9	NA	100.0	NA	NA	0.7	NA	0.0	3.5	0.0	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	30301025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	NA	0.0	1.3	0.0	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	30302025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0.0	NA	0.0	0.9	0.0	4
ParaHIT® - f (Device)[j]	55IC102-50	Span Diagnostics Ltd.	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
ParaHIT® -f (Dipstick)[j]	55IC101-50	Span Diagnostics Ltd.	80.8	NA	99.0	NA	NA	0.0	NA	1.4	2.5	0.0	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[k]	05FK90	Standard Diagnostics Inc.	87.9	NA	100.0	NA	NA	0.0	NA	0.0	2.0	0.0	3
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	97.5	NA	98.7	NA	NA	0.0	NA	0.0	2.4	0.0	1
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.94	5.2 (230)	0.7	4
Wondfo One Step Malaria P.f Test[j]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	89.8	NA	99.0	NA	NA	0	NA	0	0.4 (231)	0.2	4

Table S1 *(continued)*

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%) (n=1192)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non Pf infection[e]	False-positive Pf infection[f]	False-positive non Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
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	3
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0	4
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	4.2	0.0	1
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[k]	MFV-124F	AZOG, INC.	62.2	0.0	98.0	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3	4
Binax 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	0.3	1
BIONOTE MALARIA P.f.& 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	3.0 (199)	0.1	3
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, Inc.	83.8	94.3	100.0	97.1	2.3	1.4 (139)	0.0 (194)	1.4	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	1
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, Inc.	88.9	91.4	100.0	100.0	1.3	0.7	6.1	0.0	0.5	0.0	3
CareStart™ Malaria Screen	GO231	Access Bio, Inc.	86.9	88.6	100.0	100.0	1.8	2.1	0.0	0.0	2.5 (199)	0.1	3
Clearview® Malaria Combo[j]	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	3
Clearview® Malaria Dual Test Device[j]	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	3
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	100.0	29.4	0.0	33.8	0.0	42.7	32.2 (230)	0.3	4
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	3
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	76.5	11.8	99.0	94.1	0.3 (391)	2.2	0.0	0.0	3.5 (231)	0.3	4
First Response® Malaria pLDH/HRP2 Combo Test[j]	I16FRC30	Premier Medical Corporation Ltd.	84.0	75.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	2
FirstSign™ ParaView (Pan+Pf)[j]	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0	4
Hexagon Malaria Combi	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	1
HiSens Malaria Ag P.f/P.v 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	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	2
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	0.0	100.0	0.0	0.0	99.3	0.0	98.5	97.8	0.0	4
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	3
ICT MALARIA COMBO[j]	ML02	ICT INTERNATIONAL	76.5	5.9	99.0	88.2	0.5	0.7	0.0 (195)	1.5	0.4	0.1	4
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	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	1
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	94.9	61.8	100.0	85.3	0.0	2.2	0.0	5.9	1.3	0.0	4
Malaria P.F/Vivax	17211OP-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	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	3
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[j]	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	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	63.3	2.9	100.0	85.3	0.0	0.0 (135)	0.0	0.0	0.0	0.1	4
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	3
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	39.8	2.9	94.9	97.1	0.3	0.7	0.0	0.0	0.0	0.0	4
Malascan™ Device - Rapid test for Malaria Pf/Pan[j]	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	3
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	84.7	0.0	100.0	76.5	0.0 (391)	2.2	0.0	1.5	1.3	0.1	4
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	99.0	0.0	0.0 (391)	0.0	0.0	1.5	0.9	0.1	4
NanoSign Malaria pf/pan Ag 3.0[j]	RMAP10	Bioland Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0	4

Table S1 *(continued)*

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%) (n=1192)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples		
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non Pf infection[e]	False-positive Pf infection[f]	False-positive non Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
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	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	1
One Step Malaria P.f/Pan Test[j]	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	3
OnSight™ – 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	1
OnSite Pf/Pan Ag Rapid Test[j]	R0113C	CTK Biotech, Inc.	74.5	88.2	98.0	97.1	0.0	0.0	0.0	1.5	0.0	0.0	4
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	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	84.7	82.4	99.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	76.5	61.8	100.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0	4
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	2
Parahit-Total Device Rapid test for *P. falciparum* 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	1
Parascreen® - Rapid test for Malaria Pan/Pf[j]	50310025	Zephyr Biomedicals	99.0	26.5	100.0	23.5	0.0 (391)	30.2	0.0	50.0	26.7	0.3	4
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	1
SD BIOLINE Malaria Ag P.f/Pan[j]	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	3
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	90.8	94.1	100.0	100.0	1.0 (385)	0.0 (130)	0.0 (195)	0.0 (67)	1.3 (226)	2.8	4
SD BIOLINE Malaria Ag[j]	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0	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	3
Pf and Pv													
Advanced Quality™ One Step Malaria P.f/P.v 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	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	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	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[j]	G0161	Access Bio, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[j]	G0171	Access Bio, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
Core™ Malaria Pv/Pf	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
diagnosticks- Malaria (Pv/Pf) Cassette	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
FalciVax™ - Rapid test for Malaria Pv/Pf[j]	50300025	Zephyr Biomedicals	98.0	88.2	100.0	100.0	0.8	2.9	0.0	2.9	7.3	0.0	4
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	48.1	0.0	98.7	85.0	1.0	3.8	NA	5.0	0.0 (167)	0.0	1
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	100.0	94.1	0.3 (391)	0.0	0.5	0.0	0.4	0.1	4
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	100.0	91.2	0.0	0.0	0.5	0.0	0.0	0.0	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	100.0	100.0	0.5	0.7	0.5	1.5	1.3	0.0	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	92.9	26.5	0.5	0.0 (135)	3.1 (195)	1.5	0.0 (230)	0.5	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	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
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.8	0.0	94.9	5.9	0.8	0.7	0.5	0.0	0.9	0.0	4
Maleriscan® Malaria Pf/Pv	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
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	50.0	0.0	95.9	91.2	0.0	2.9	0.0	1.5	1.3	0.0	4
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	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
OnSite Pf/Pv Ag Rapid Test[j]	R0112C	CTK Biotech, Inc.	79.6	100.0	100.0	100.0	1.5	0.0	2.0	0.0	1.3	0.0	4

Table S1 *(continued)*

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%) (n=1192)	Round
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 or 5000 parasites/µl		Clean-negative samples		
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples			
							False-positive non Pf infection[e]	False-positive Pf infection[f]	False-positive non Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	100.0	100.0	0.0	0.7	0.0	1.5	4.3	0.0	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[k]	05FK100	Standard Diagnostics Inc.	96.9	97.1	100.0	100.0	0.3	0.0	0.5	0.0	2.2	0.0	4
SD BIOLINE Malaria Ag Pf/Pv	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
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	99.0	100.0	13.3	27.4 (135)	16.0 (194)	19.4 (67)	32.0 (231)	0.5	4
Pf, Pv and Pan													
Core™ Malaria Pan/Pv/Pf	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
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	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
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	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
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	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
Pan only													
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	72.2	100.0	100.0	100.0	NA	NA	NA	NA	1.8	0.0	1
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0	99	55.9	NA	NA	NA	NA	2.2	0.2	4
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	92.4	100.0	100.0	100.0	NA	NA	NA	NA	6.6	0.0	1
Clearview® Malaria pLDH[j]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	81.8	85.7	99.0	100.0	NA	NA	NA	NA	13.5	0.5	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	NA	NA	NA	NA	0.0	0.3	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	31.0	92.5	98.0	100.0	NA	NA	NA	NA	0.0	0.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	25.0	82.5	87.0	100.0	NA	NA	NA	NA	2.5	0.2	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	22.0	77.5	96.0	100.0	NA	NA	NA	NA	2.5	0.2	2
Parabank™ Device - Rapid test for Malaria Pan[j]	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	NA	NA	NA	NA	0.5	0.2	3
Pv only													
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	92.5	NA	100.0	0.3	NA	1.0	NA	1.0	0.0	2

NA, not applicable

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

[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] The total number of times a positive result for malaria was generated when it should not have been

[c] Round 1, n=79; Round 2, n=100; Round 3, n=99; Round 4, n=98

[d] Round 1, n=20; Round 2, n=40; Round 3, n=35; Round 4, n=34

[e] For combination tests, Pan or Pv line, only, positive indicates a false-positive non *P. falciparum* infection (Round 1 n=316; Round 2, n=400; Round 3, n=396; Round 4, n=392)

[f] Pf line positive indicates a false-positive *P. falciparum* infection (Round 1, n=80; Round 2, n=160; Round 3, n=140; Round 4, n=136)

[g] For combination tests, Pan or Pv line, only, positive indicates a false-positive non-*P. falciparum* infection (Round 1, n=158, Round 2, n=200; Round 3, n=198; Round 4, n=196)

[h] Pf line positive indicates a false-positive *P. falciparum* infection (Round 1, n=40; Round 2, n=80, Round 3, n=70; Round 4, n=68)

[i] Round 1, n=168; Round 2, n=200; Round 3, n=200; Round 4, n=232

[j] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S3.

[k] PDS presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH). For test line specific results refer to the tables and annexes in the full reports.

Detection rate (%)	≥95	85-94	50-84	< 50
False-positive rate (%)	<2	2-5	6 -10	>10
Invalid rate (%)	<1% of tests conducted	1-2% of tests conducted	2-5% of tests conducted	>5% of tests conducted

Table S2: Malaria RDT Rounds 1—4 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 *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pan line)			Percent positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	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			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf only															
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	15.0	17.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Advanced Quality™ One Step Malaria P.f Test[a]	ITP11002TC40	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Advanced Quality™Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	80.0	95.0	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	95.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	86.7	100.0	90.0	80.0	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
Clearview® Malaria P.f.[a]	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	95.0	70.0	55.0	95.0	95.0	95.0	NA	NA	NA	NA	NA	NA	2
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	20.0	15.0	0.0	100.0	90.0	95.0	NA	NA	NA	NA	NA	NA	1
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Hexagon Malaria	58051	Human GmbH	50.0	35.0	60.0	95.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
ICT Diagnostics Malaria P.f.[a]	ML01	ICT Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Immunoquick Malaria Falciparum	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	100.0	100.0	86.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
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	NA	NA	NA	NA	NA	NA	1
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
One Step Malaria P.F Test (Cassette)[a]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	100.0	95.0	90.0	100.0	100.0	65.0	NA	NA	NA	NA	NA	NA	2
OnSite Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	30301025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	30302025	Orchid Biomedical Systems	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaHIT® - f (Device)[a]	55IC102-50	Span Diagnostics Ltd.	100.0	96.7	100.0	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	3
ParaHIT® -f (Dipstick)[a]	55IC101-50	Span Diagnostics Ltd.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[b]	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	1
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Wondfo One Step Malaria P.f Test[a]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
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	0.0	0.0	3
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pan line)			Percent positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	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			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
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	100.0	100.0	1
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b]	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
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	95.0	75.0	1
BIONOTE MALARIA P.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	100.0	90.0	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	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	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	100.0	100.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	100.0	100.0	93.3	100.0	100.0	100.0	100.0	100.0	93.3	100.0	100.0	100.0	3
Clearview® Malaria Combo[a]	VB11	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	20.0	0.0	3
Clearview® Malaria Dual Test Device[a]	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	90.0	20.0	3
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	26.7	80.0	83.3	100.0	100.0	100.0	4
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	100.0	90.0	90.0	3
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	70.0	4
First Response® Malaria pLDH/HRP2 Combo Test[a]	I16FRC30	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	85.0	55.0	55.0	100.0	100.0	100.0	2
FirstSign™ ParaView (Pan+Pf)[a]	2101CB-25	Unimed International Inc.	96.7	100.0	100.0	100.0	100.0	100.0	0.0	0.0	13.3	100.0	100.0	100.0	4
Hexagon Malaria Combi	58024	Human GmbH	65.0	55.0	50.0	100.0	85.0	95.0	0.0	0.0	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	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0	100.0	100.0	100.0	2
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	76.7	100.0	100.0	100.0	100.0	100.0	4
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	80.0	0.0	3
ICT MALARIA COMBO[a]	ML02	ICT INTERNATIONAL	96.7	96.7	93.3	100.0	100.0	100.0	3.3	20.0	13.3	100.0	50.0	70.0	4
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	50.0	100.0	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	80.0	80.0	1
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	20.0	3.3	33.3	100.0	100.0	100.0	4
Malaria P.F/Vivax	17211OP-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	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	60.0	40.0	3
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[a]	MFV-124R	AZOG, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	100.0	96.7	96.7	100.0	100.0	100.0	16.6	0.0	0.0	90.0	40.0	50.0	4
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	0.0	0.0	3
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	56.7	23.3	26.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	90.0	50.0	4
Malascan™ Device - Rapid test for Malaria Pf/Pan[a]	50402025	Zephyr Biomedical Systems	96.7	100.0	96.7	100.0	100.0	100.0	0.0	0.0	6.7	100.0	100.0	100.0	3
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
NanoSign Malaria pf/pan Ag 3.0[a]	RMAP10	Bioland Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
NanoSign Malaria Pf/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	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	50.0	5.0	1
One Step Malaria P.f/Pan Test[a]	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	80.0	100.0	3
OnSight™ – 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	100.0	95.0	1
OnSite Pf/Pan Ag Rapid Test[a]	R0113C	CTK Biotech, Inc.	100.0	100.0	93.3	100.0	100.0	100.0	0.0	3.3	0.0	70.0	20.0	10.0	4

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pan line)			Percent positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	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			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
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	90.0	0.0	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	100.0	93.3	46.7	100.0	100.0	60.0	50.0	0.0	0.0	100.0	90.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	55.0	85.0	55.0	100.0	100.0	95.0	10.0	0.0	0.0	50.0	45.0	70.0	2
Parahit-Total Device Rapid test for *P. falciparum* 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	0.0	0.0	1
Parascreen® - Rapid test for Malaria Pan/Pfa	50310025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	86.6	13.3	83.3	100.0	100.0	100.0	4
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	50.0	5.0	1
SD BIOLINE Malaria Ag P.f/Pan[a]	05FK60	Standard Diagnostics Inc.	100.0	96.7	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	70.0	90.0	3
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	96.7	96.7	100.0	90.0	100.0	100.0	16.6	10.0	0.0	90.0	100.0	100.0	4
SD BIOLINE Malaria Ag[a]	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	100.0	80.0	90.0	0.0	0.0	0.0	80.0	20.0	90.0	3
Surestep™ Easy Malaria Pf/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	0.0	0.0	3
Pf and Pv															
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	100.0	96.7	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	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	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[a]	G0161	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[a]	G0171	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	100.0	95.0	95.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
FalciVax™ - Rapid test for Malaria Pv/Pf[a]	50300025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	95.0	70.0	0.0	100.0	95.0	75.0	NA	NA	NA	NA	NA	NA	1
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	100.0	100.0	100.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
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	NA	NA	NA	NA	NA	NA	3
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.0	33.3	40.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	100.0	60.0	30.0	100.0	90.0	95.0	NA	NA	NA	NA	NA	NA	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	40.0	6.7	0.0	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	4
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	NA	NA	NA	NA	NA	NA	2
OnSite Pf/Pv Ag Rapid Test[a]	R0112C	CTK Biotech, Inc.	100.0	100.0	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b]	05FK100	Standard Diagnostics Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	100.0	100.0	36.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pan line)			Percent positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	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			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
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	80.0	50.0	70.0	3
diagnosticks 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	70.0	0.0	50.0	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	100.0	90.0	100.0	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	100.0	95.0	100.0	2
Pan Only															
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	50.0	65.0	70.0	100.0	100.0	100.0	1
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	4
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	90.0	100.0	100.0	100.0	1
Clearview® Malaria pLDH[a]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	NA	NA	NA	NA	NA	NA	96.7	93.3	100.0	100.0	100.0	100.0	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	80.0	100.0	80.0	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	NA	NA	NA	NA	NA	NA	50.0	80.0	55.0	100.0	100.0	100.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA	25.0	5.0	10.0	100.0	100.0	100.0	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	NA	NA	NA	NA	NA	NA	5.0	35.0	15.0	100.0	100.0	100.0	2
Parabank™ Device - Rapid test for Malaria Pan[a]	50301025	Zephyr Biomedical Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	90.0	100.0	100.0	3
Pv only															
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2

NA, not applicable

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

[a] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S3.

[b] 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 is presented in the following table:

Product	Catalogue number	Manufacturer	Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pan line)			Percent positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	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			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) - (PF(HRP2) line)	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)- (PF(pLDH) line)	05FK90	Standard Diagnostics Inc.	0.0	0.0	0.0	33.3	33.3	33.3	NA	NA	NA	NA	NA	NA	3
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(HRP2) line)	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(pLDH) line)	MFV-124F	AZOG, INC.	13.3	3.3	6.7	50.0	10.0	50.0	3.3	0.0	0.0	20.0	0.0	0.0	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv - (PF(HRP2) line)	05FK100	Standard Diagnostics Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv - (PF(pLDH) line)	05FK100	Standard Diagnostics Inc.	26.7	3.3	3.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4

Table S3: Product Resubmissions: WHO Malaria RDT Product Testing – Rounds 1–4

Manufacturer	Initial Testing			Subsequent Testing		
	Round	Product Name	Catalogue No.	Round	Product Name	Catalogue No.
Access Bio, Inc.	2	CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	4	CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161
	2	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	4	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171
AZOG	1	Malaria Pf (HRPII)/pv-LDH) Antigen Detection Test Device[a]	MFV-124R	3	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R
Bioland	3	NanoSign Malaria Pf/Pan Ag	RMAP10	4	NanoSign Malaria Pf/Pan Ag	RMAP10
Blue Cross Bio-Medical (Beijing) Co., Ltd.	2	One Step Malaria Pf Test (cassette)	522352	3, 4	One Step Malaria P.F 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, 4	OnSite Pf/Pan Malaria Ag Rapid Test	R0113C
	2	Onsite Pf/Pv Ag Rapid Test	R0112C	3, 4	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C
DiaMed - A Division of Bio-Rad	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 P.f./Pan Whole Blood Test	W56-C
	2	One Step Malaria P.f Test[b]	W37-C (4.0mm)	3, 4	One Step Malaria P.f Test	W37-C
ICT Diagnostics (R & R Marketing)	1	ICT Malaria Combo Cassette Test	ML02	3, 4	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 P.f Test	ITP11002 TC40
Orchid Biomedical Systems	1	Paracheck Pf Rapid test for *P. falciparum* Malaria (Device)	30301025	3, 4	Paracheck® Pf Device - Rapid test for *P. falciparum* Malaria (Ver. 3)	30301025
	1	Paracheck Pf Rapid test for *P. falciparum* Malaria (Dipstick)	30302025	3, 4	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver.3)	30302025
Premier Medical Corporation Ltd.	1	First Response Malaria Ag Combo (pLDH/HRP2)	II6FRC30	2	First Response® Malaria Ag Combo (pLDH/HRP2)	I16FRC30
Span Diagnotics Ltd.	1	Parahit-f TEST DEVICE FOR FALCIPARUM MALARIA	25975	3	ParaHIT® - f (Device)	55IC102-10
	1	Parahit-f DIPSTICK FOR FALCIPARUM MALARIA	25977	3	ParaHIT® - f (Dipstick)	55IC101-10
Standard Diagnostics Inc.	1	SD BIOLINE Malaria Ag	05FK40-02-5[d]	3	SD BIOLINE Malaria Ag	05FK40
	1	SD BIOLINE Malaria Ag Pf/Pan	05FK60-02-3[d]	3	SD BIOLINE Malaria Ag P.f/Pan	05FK60
Unimed International Inc.	2	FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	4	FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25
Vision Biotech (Pty) Ltd (now Alere Healthcare (Pty) Ltd)	1	Malaria Rapid Combo	VB011	3	Clearview® Malaria Combo	VB11[e]
	1	Malaria Rapid Pf	VB01	3	Clearview ®Malaria Pf	VB01
	1	Malaria Rapid Dual	VB020	3	Clearview® Malaria Dual Test Device	VB20[e]
Zephyr Biomedical Systems	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, 4	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025
	2	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	4	Falcivax™ Rapid Test for Malaria Pv/Pf (device)	50300025

[a] 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. No change in product code.

[b] In Round 2, product did not pass Phase 1, therefore results do not feature in summary tables.

[c] Error in WHO Malaria RDT Product Testing: Round 1 report: product code (II6FRC30) should have been (I16FRC30), as in Round 2

[d] 02-05/02-03 suffix refers to version of the package inserts

[e] New company acquisition (Alere™) - hence name and product code changes. Manufacturer confirmed compliance with product definition.

2. WHO MALARIA RDT PRODUCT TESTING: ROUND 4 EXECUTIVE SUMMARY

2.1. Introduction

The World Health Organization estimates that half the world's population is at risk of malaria, with an estimated 216 million people (range 149–274 million) developing clinical malaria in 2010 (81% in Africa), and 655,000 deaths (range 537,000–907,000) due to malaria (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 confirmed, resulting in over-use of anti-malarial drugs and poor disease monitoring (*1*).

WHO recommends that malaria case management be based on parasite-based diagnosis in all cases (*2*). The use of antigen-detecting rapid diagnostic tests (RDTs) forms a vital part of this strategy, by providing the possibility of 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), the 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. Currently, these data are guiding procurement decisions which are in turn, shifting markets towards better performing tests and helping to drive overall improvement in the quality of manufacturing. The results of WHO Malaria RDT Product Testing have been published annually since 2009 and presently form the basis of procurement criteria of the WHO, other UN agencies ,the Global Fund and national governments (*3*).This Report provides data on Round 4 of Product Testing, performed at the United States Centers for Disease Control and Prevention, Division of Malaria and Parasitic Diseases (CDC) in 2011-2012. It provides performance data on 48 products. This evaluation should be seen as additive to Rounds 1-3 evaluations (*3-5*). The four reports should be viewed together as a single evaluation, with the exception that where products tested in previous rounds have been re-submitted for testing in Rounds 2, 3 or 4, the most recent result replace those reported previously. From round to round, the evaluation panels are essentially equivalent[1], and the same testing protocols are followed. This report expands the data set from previous rounds, and therefore increases the number of RDTs available for procurement that have detailed comparative data on aspects of performance relevant to field use.

2.2. The WHO Product Testing Programme

Product Testing is part of the WHO-FIND Malaria RDT Evaluation Programme. This programme develops methods for evaluation and provides relevant data on antigen-detecting malaria rapid diagnostic tests. The programme is a collaboration of many institutions in malaria-endemic and non-endemic countries, with the global specimen bank maintained, and the testing performed, at CDC (Figure 2).

All companies manufacturing under ISO 13485:2003 Quality System Standard were invited to submit up to two tests for evaluation under the programme. The 44 products and 4 co-listed products from 27 manufacturers[2] were evaluated against prepared blood panels of cultured *Plasmodium falciparum* parasites and patient-derived, wild-type *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. As in previous rounds, RDTs are grouped in the result tables and figures into those detecting *P. falciparum* only, various combination tests, and those that have only a pan-specific (or *P. vivax*-specific) line. Manufacturers submitted two lots of each product for evaluation.

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 fifth round of

[1] *http://www2.wpro.who.int/sites/rdt/who_rdt_evaluation/* (accessed 10 October 2012)

[2] Several manufacturers are subsidiaries of Alere™ and two companies (Access Bio, Ethiopia and Medisenor, Inc) sell re-branded products manufactured by Access Bio, Inc (Table 1). These re-branded/joint listed products were actually not evaluated as they are identical to CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO (G0161) and CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO (G0171)

product testing will begin in January 2013, and results will be published in 2014.

2.3. Results of the evaluation

The results (summarized in Tables 3, 4, 5 and Figures 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), considered close to the threshold that tests must detect to reliably identify clinical malaria in many settings *(6)*, and a higher parasite density (2000 (or 5000) parasites/µl). For the purposes of this report, the main measure of performance is the 'panel detection score (PDS)'; 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.

Consistent with the performance of products included in previous rounds of Product Testing, the PDS varies widely between products, with some products showing high performance in detecting parasites, in thermal stability and other performance measures. Overall, there is no obvious trade-off seen between PDS (or positivity rate) and false-positive rate, these being surrogates for sensitivity and specificity in the field, respectively. Furthermore, a number of tests showed good outcomes on both of these indicators. Sixty nine per cent *(9/13)* of the re-submitted products either maintained or improved their PDS and overall there was a mean increase in *P. falciparum* PDS of 3.7. Against the *P. vivax* panels, the mean PDS increase was 13.4. However, for combination tests, some improvements in *P. falciparum* or *P. vivax* detection were associated with decreases in the PDS for the other. A few products have very high *P. falciparum* false-positive rates against clean-negatives and, as previously reported, high false-positive rates are seen for several products against the blood samples containing specific immunological abnormalities (e.g. rheumatoid factor, anti-mouse antibodies). However, the number of samples evaluated was small and the clinical significance of these results is limited, but may become important in certain populations with very low parasite prevalence. Some products show a variation in performance indicators between the two lots evaluated, underlining the advisability of lot-testing before field use. Heat (thermal) stability varies widely, with some products retaining high positivity rates after two months storage at 45°C in 75% humidity. For many products, pan-line performance at baseline and post-heat stress for detection of the *P. falciparum* isolate is poor, and nearly universally poor against low parasite density samples, making true stability difficult to assess.

The clinical sensitivity of an RDT to detect malaria is highly dependent on the local conditions, including parasite density in the target population, and so will vary among populations with differing levels of transmission. The results in this report show comparative performance between RDTs, and give an idea 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 panel detection score 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.

In areas where significant levels of non-expression of HRP2 are known to occur, the results of HRP2-detecting tests given in this report should not be considered predictive of field sensitivity. Tests targeting *P. falciparum* by detection of pLDH or aldolase should only be considered.

Heat stability (summarized in Table 5) 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 during transport and storage have demonstrated good 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 needs to be placed on stability at high temperatures.

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.

2.4. Use of these results

The results included in this report should be considered together with those of previous Rounds 1-3, with the results of re-submitted products replacing those reported in earlier rounds *(3-5)*. Ultimately, 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). 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. This report provides an algorithm to assist in this decision-making process (Annex 5a). Furthermore, comprehensive guidance on several aspects of procurement can be found in '*Good Practices for selecting and procuring rapid diagnostic tests for malaria*' *(7)*.

3. BACKGROUND

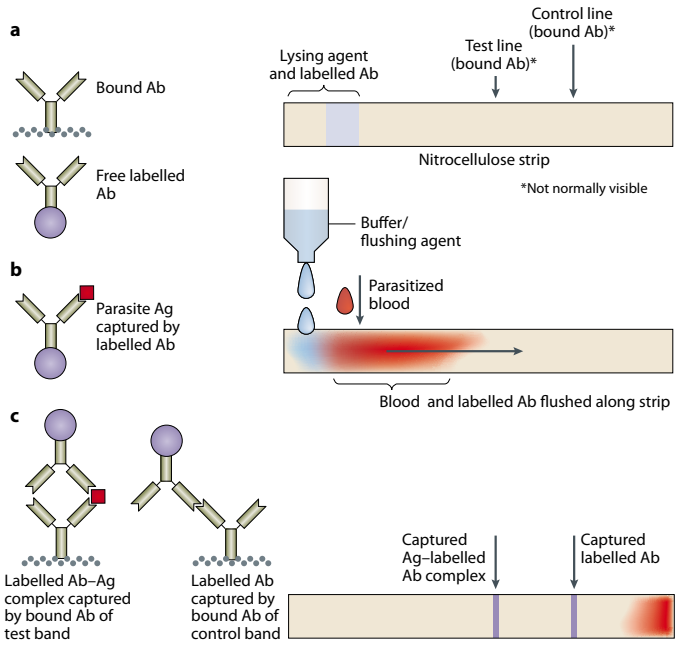
In 2011, WHO estimated that 3.3 billion persons were at risk of acquiring malaria. Of these, 216 million people (range 149–274 million) developed clinical malaria in 2010 (81% in Africa), and 655,000 died (range 537,000–907,000) due to malaria (91% in Africa, most being children). Malaria remains endemic in 106 countries *(1)*.

In the past decade, major new opportunities for the control of malaria have emerged, including implementation of long-lasting insecticidal nets, indoor residual spraying of insecticides and artemisinin-based combination therapy (ACT). These tools have been shown to reduce the burden of malaria infection in countries where they are adequately implemented. In turn, the proportion of febrile episodes attributable to malaria is likely to decrease substantially.

Despite WHO recommendations for laboratory-confirmed diagnosis of malaria infections prior to treatment in all cases *(2)*, diagnosis is often made on clinical grounds *(6)*. However, in most endemic areas malaria makes up a minority of 'malaria-like' febrile illness. Microscopy has been the cornerstone of diagnosis and is recommended for malaria diagnosis where its quality can be maintained; however, the need for trained personnel, adequate reagents and equipment, limit its availability and accessibility to many people in malaria-endemic areas. Rapid, accurate and accessible diagnostic tools are becoming increasingly important, as programmes expand parasite-based diagnosis and the prevalence of malaria decreases. In recent years, rapid diagnostic tests (RDTs), which detect *Plasmodium*-specific antigens (proteins) in whole blood of infected people, have emerged as an attractive alternative to microscopy. Currently available RDTs come in various formats (dipstick, cassette or card) and contain bound antibodies to specific antigens such as histidine-rich protein-2 (HRP2) (specific to *P. falciparum*), pan-specific or species-specific *plasmodium* lactate dehydrogenase (pLDH) or aldolase (specific to all the major *Plasmodium* species: *P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale* (Figure 1).

To be widely useful, a RDT must have high sensitivity to ensure all clinically-significant malaria infections are detected; high specificity to enable monitoring of low malaria prevalence and appropriate management of non-malarial fever; and high stability to allow transport and storage in ambient conditions in malaria-endemic areas. Published field trials of RDTs show high variability in performance, likely due to inadequate quality of manufacture, incorrect storage and handling, poor preparation and interpretation, and sometimes poor study methods, analysis and reporting *(8-16)*. In general, diagnostic testing (by microscopy or RDT) to a level of 200 parasites/µl will reliably detect nearly all clinically relevant infections in malaria-endemic areas *(6)*.

Figure 1: Mode of action of antigen-detecting malaria RDTs



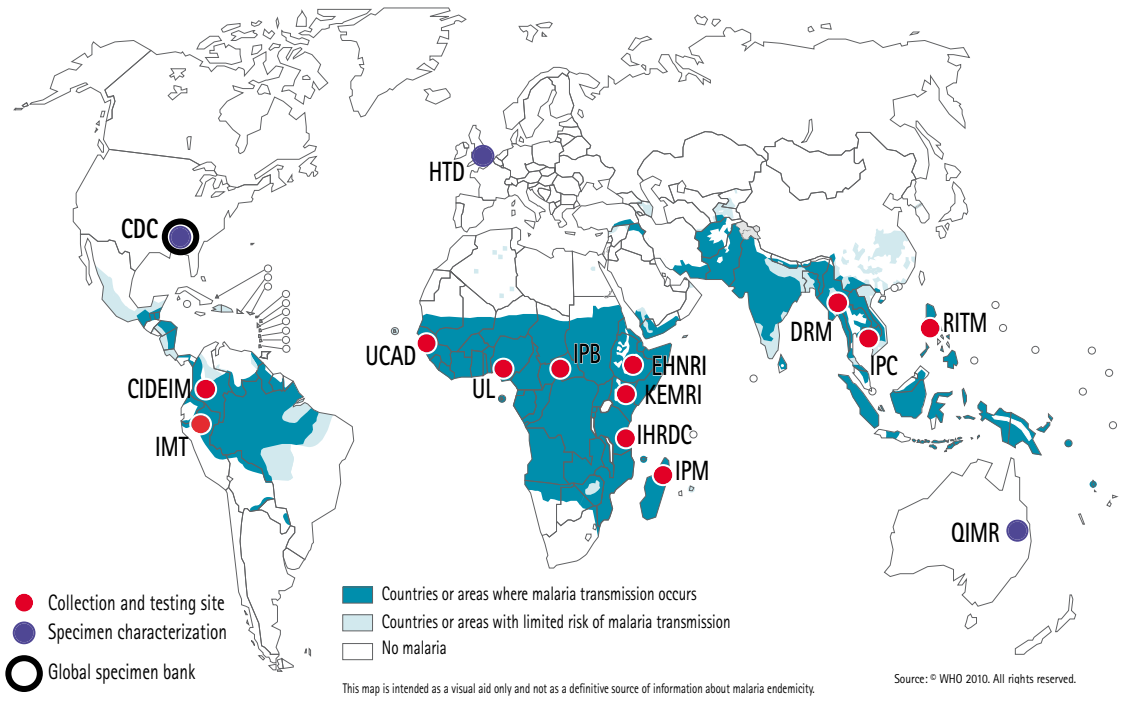
Mode of action of common malaria RDT format:

(a) Dye-labeled antibody (Ab), specific for target antigen, is present on the lower end of the nitrocellulose strip or in a well provided with the strip. Antibody, also specific for the target antigen, is bound to the strip in a thin (test) line, and either antibody specific for the labeled antibody, or antigen, is bound at the control line.

(b) Blood and buffer, which have been placed on the strip or in the well, are mixed with the labeled antibody and are drawn up the strip across the lines of bound antibody.

(c) If antigen is present, some labeled antibody will be trapped on the test line. Other labeled antibody is trapped on the control line.

Figure 2: Network of specimen collection, characterization and testing sites



Abbreviations: CDC Centers for Disease Control and Prevention (Atlanta, United States of America); CIDEIM Centro Internacional de Entrenamiento y Investigaciones Médicas (Cali, Colombia); DMR Experimental Medicine Research Division (Department of Medical Research, Yangon, Myanmar); EHNRI Ethiopian Health and Nutrition Research Institute (Addis Ababa, Ethiopia); HTD Hospital for Tropical Diseases (London, United Kingdom of Great Britain and Ireland); IHRDC Ifakara Health Research and Development Center (Bagamoyo, The United Republic of Tanzania); IMT Instituto de Medicina Tropical (Universidad Peruana Cayetano Heredia, Lima, Peru); IPB Institut Pasteur de Bangui (Bangui, Central African Republic); IPC Institut Pasteur du Cambodge (Phnom Penh, Cambodia); IPM Institut Pasteur de Madagascar (Antananarivo, Madagascar); KEMRI: Kenya Medical Research Institute (Kisumu, Kenya); QIMR Queensland Institute of Medical Research (Brisbane, Australia); RITM Research Institute of Tropical Medicine (Manila, The Philippines); UCAD: Université Cheikh Anta DIOP (Dakar, Senegal); UL University of Lagos (Lagos, Nigeria).

The number of RDTs available on the market has grown rapidly since their introduction in the late 1990s. It is estimated that there are 60 brands and over 200 tests commercially available today, with an estimated 155 million tests or more financed in 2011[1, 2]. However, regulatory oversight of diagnostics is often weak, and procurement agencies have faced considerable problems in selecting appropriate RDTs and ensuring quality. In view of the inconsistency in field study results and the inherent difficulties in assessing large numbers of products in a standardized way through field trials, WHO and various partners embarked on a Malaria Rapid Diagnostic Test Product Evaluation Programme in 2002 to develop and employ standardized assessment of malaria RDT performance, and to guide procurement decisions and regulatory mechanisms. The Programme has been overseen by WHO and TDR in partnership with FIND, and has been guided by a Steering Committee and technical consultations from 2003 to 2012 overseeing the development of standard operating procedures (SOPs) for the programme *(17, 18)*.

A network of specimen collection sites was established to contribute specimens to a global bank at the CDC and to facilitate local quality control activities (Figure 2).

The reports of the first, second and third rounds of Product Testing were released in 2009, 2010 and 2011, respectively *(3–5)*. This fourth report adds performance data on 35 new products and updated data on 13 re-submitted RDTs. Testing for Round 4 was conducted against an evaluation panel with similar characteristics in terms of overall antigen concentration, parasite origin, and parasite-negative blood samples, to previous panels[3]. The majority of panel samples were retained from previous rounds. The results should be considered together with those from Round 1–3 *(3–5)*.

[1] *Tracking Progress in Scaling-Up Diagnosis and Treatment for Malaria*. Geneva. 2009. Roll Back Malaria Partnership.

[2] J. Cunningham, unpublished data.

[3] *http://www2.wpro.who.int/sites/rdt/who_rdt_evaluation/* (accessed 10 October 2012)

4. OBJECTIVE

The objective of the programme is to evaluate malaria RDTs to produce performance data to guide procurement of RDTs for use in the field in malaria-endemic countries.

5. MATERIALS AND METHODS

5.1. Test selection

In December 2010, the WHO-FIND Malaria RDT Evaluation Programme issued a call for expression of interest to manufacturers of malaria RDTs along with information regarding the requirements for submission of a product to Round 4 and the conditions for participation in the Evaluation Programme[1]. Requirements included: valid ISO 13485:2003 certification from all manufacturing sites, supply of sufficient quantities of products (1100 tests from each of 2 lots), compliance with the product definition[2] and deadlines for document submission.

Thirty manufacturers, including 82 products, responded to the call. In order to keep to schedule and budget, manufacturers were asked to limit their product submissions to two. The final number of products included in Round 4 was 48, including 4 joint listed products[3]. Based on catalogue numbers and verification with manufacturers, 13 of the 48 products (27%) were previously submitted to one or more rounds (Table S3). After initial evaluation against the *P. falciparum* culture-derived panel (Phase 1), two products did not meet minimum performance requirements[4] and therefore did not proceed to the full evaluation.

In summary, of the 46 products fully evaluated: 10 are designed to detect *P. falciparum* alone, 35 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria , as well as *P. falciparum* and *P.vivax* or *P. vivax, ovale, malariae* (vom)-specific, and 1 to detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them. Annexes 1 and 2 provide a comprehensive overview of product characteristics.

5.2. Outline of the Product Testing Protocol

The testing process is outlined in Figure 3 and in the *Methods Manual for Product Testing of Malaria Rapid Diagnostic Tests - Version 5 (17)*. In brief, RDTs from each of two lots of each product were evaluated against a panel of parasite-positive and parasite-negative cryo-preserved blood samples, and a panel of parasite-negative samples. Both lots were also tested for heat (thermal) stability, evaluated before and after two months' storage at 4°C, 35°C and 45°C. Finally, an ease-of-use description was completed using a standard assessment format.

The testing process and all results were overseen by the WHO-FIND Malaria RDT Evaluation Programme Steering Committee, and manufacturers were given 60 days to comment on individual product results prior to publication.

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1 *http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/call_for_testing_round4.htm*

2 Working definition of a product can be found here in Annex 2: *http://www2.wpro.who.int/NR/rdonlyres/2E4CFDF2-90BC-433C-B22D-7E42634EABB7/0/EOIAnnex1_2_3_Round4final171210.pdf* (accessed 10 October 2012)

3 See Table 1

4 PDS > 80% against high density (2000p/µl) *P. falciparum* culture samples

Table 1: Manufacturers and products accepted into Round 4 of WHO Malaria RDT Product Testing Programme

Manufacturer	Product Name	Catalogue Number[a]	Target antigen(s)		
ABON Biopharm (Hangzhou) Co. Ltd[b]	ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	HRP2		
	ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	aldolase	HRP2	
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[c]	G0161	pvpLDH	HRP2	
	CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[c]	G0171	pvompLDH	HRP2	
Access Bio Ethiopia	ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO[d]	G0161	pvpLDH	HRP2	
	ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO[e]	G0171	pvompLDH	HRP2	
Advy Chemical Private Limited (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	panpLDH	HRP2	
Artron Laboratories Inc.	Trusty™ Malaria Antigen P.f. test	A03-11-322	HRP2		
	Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	pvpLDH	HRP2	
AZOG, INC.	AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	panpLDH	pfpLDH	HRP2
	AZOG hCG Malaria Detection Test Device	MPT-124	hCG	HRP2, pf-pLDH, panpLDH	
Bhat Bio-Tech India (Pte.) Ltd.	Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	HRP2		
	Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	panpLDH	HRP2	
Bioland Ltd.	NanoSign Malaria pf/pan Ag [c]	RMAP10	panpLDH	HRP2	
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (Cassette) [c]	522352	HRP2		
	One Step Malaria P.F/P.V Test (Cassette)	523352	pvpLDH	HRP2	
Core Diagnostics Ltd.	Core Malaria Pan Pf	MAL-190024	panpLDH	HRP2	
CTK Biotech, Inc.	OnSite Pf/Pv Ag Rapid Test [c]	R0112C	HRP2	pvpLDH	
	OnSite Pf/Pan Ag Rapid Test [c]	R0113C	HRP2	panpLDH	
Formosa Biomedical Technology Corp.	MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	panpLDH	HRP2	
Genomix Molecular Diagnostics pvt.Ltd.	Malaria Pf/Pv	GM002	pvpLDH	HRP2	
	Malaria Pf/ PAN	GM004	panpLDH	HRP2	
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo One Step Malaria P.f Test [c]	W 37-C	HRP2		
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Combo Card	HR3123	pvpLDH	HRP2	
	HiSens Malaria Ag P.f/VOM Combo Card	HR3323	pvompLDH	HRP2	
Hema Diagnostic Systems, LLC	RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/PV TEST	MAL-PFV-0207	pvpLDH	HRP2	
	RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	pvpLDH	HRP2	
Humasis, Co., Ltd.	Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	panpLDH	HRP2	
	Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	pvpLDH	HRP2	
ICT INTERNATIONAL	ICT MALARIA COMBO [c]	ML02	HRP2	aldolase	
	ICT MALARIA P.F.	ML04	pfpLDH		
IND Diagnostics Inc.	IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	panpLDH	HRP2	
	IND ONE STEP MALARIA ANTIGEN P.f	535-11	HRP2		
Medisensor, Inc.	Medisensor Malaria HRP2/pLDH (Pf/PV) COMBO[d]	M161	pvpLDH	HRP2	
	Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO[e]	M171	pvompLDH	HRP2	

Manufacturer	Product Name	Catalogue Number[a]	Target antigen(s)		
Orchid Biomedical Systems (Tulip Group)	Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[c]	30301025	HRP2		
	Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[c]	30302025	HRP2		
RapiGen inc.	BIOCREDIT Malaria pf(HRP II)	HR0100	HRP2		
Span Diagnostics Ltd.	ParaHIT - Total Ver. 1.0 Rapid Test for *P. falciparum* and Pan malaria species (Dipstick)	55IC203-10	aldolase	HRP2	
	ParaHIT - Total Ver. 1.0 Rapid Test for *P. falciparum* and Pan malaria species (Device)	55IC204-10	aldolase	HRP2	
Standard Diagnostics Inc.[b]	SD BIOLINE Malaria Ag Pf/ Pan	05FK66	panpLDH	HRP2	
	SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	pvpLDH	pfpLDH	HRP2
Unimed International Inc.	FirstSign™ Malaria Pf	2100CB-25	HRP2		
	FirstSign™ ParaView (Pan+Pf)[c]	2101CB-25	panpLDH	HRP2	
United Biotech, Inc.	Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	panpLDH	HRP2	
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	pvpLDH	HRP2	
Zephyr Biomedicals	FalciVax™ - Rapid test for Malaria Pv/Pf [c]	50300025	pvpLDH	HRP2	
	Parascreen® - Rapid test for Malaria Pan/Pf [c]	50310025	panpLDH	HRP2	

Pf, *P. falciparum* Pv, *P. vivax* Pvom, *P. vivax*, ovale, malariae HRP2, histidine-rich protein 2 pLDH, *Plasmodium* lactate dehydrogenase

[a] The same products may have different catalogue numbers to reflect box sizes and/or kit contents. Usually this involves the end portion of the product code. Please contact manufacturers for details

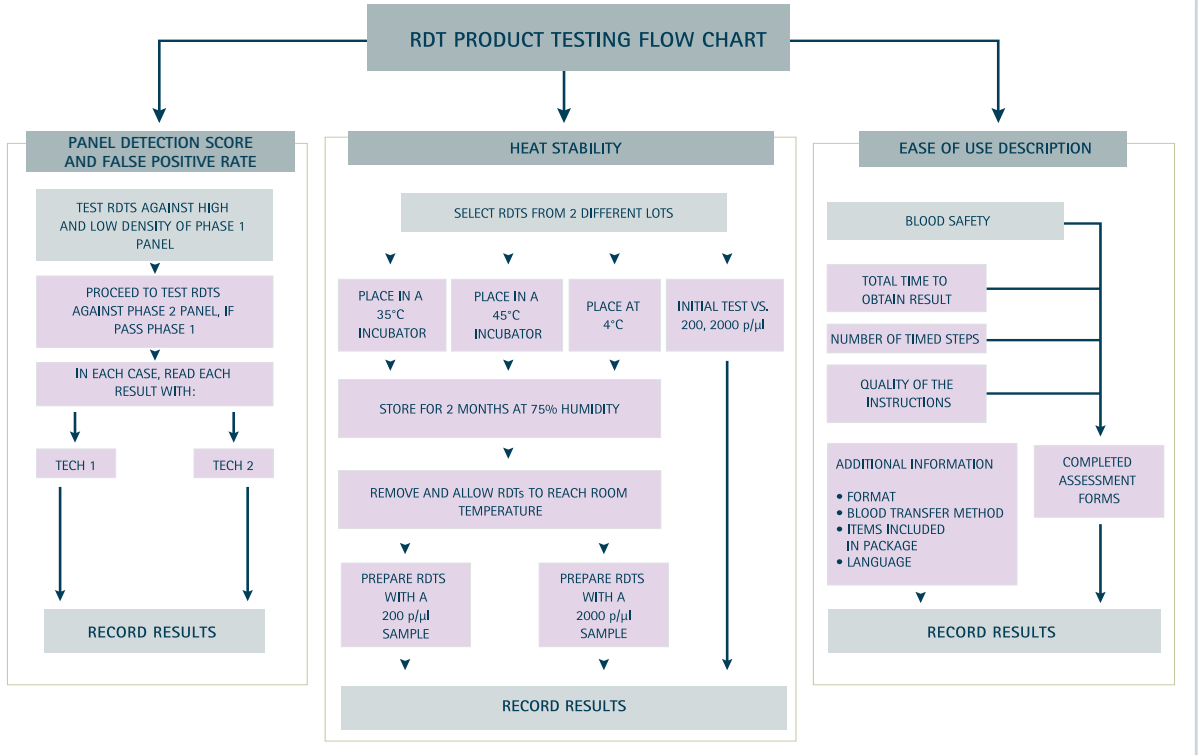
[b] Alere subsidiaries

[c] These products have also been submitted to previous rounds of WHO Malaria RDT Product Testing (Round 1-3). For details on all product resubmissions refer to Table S3.

[d] These products are joint listed (manufactured under identical conditions) with CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO (G0161, Access Bio, Inc.)

[e] These products are jointed listed (manufactured under identical conditions) with CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO (G0171, Access Bio, Inc.)

Figure 3: Malaria RDT Product Testing Overview



5.3. Evaluation panels

RDTs were evaluated against three panels, specifically:

i) *P. falciparum* culture lines (includes a subset, 'manufacturer's panel') at low (200 parasites/µl) and high parasite densities (2000 parasites/µl).

ii) Wild-type *Plasmodium* species (*P. falciparum*, *P. vivax*) from naturally infected humans and parasite-negative samples at low (200 parasites/µl) and high parasite densities (2000 (or 5000)[1] parasites/µl). All samples are prepared from isolates that express HRP2.

iii) Parasite-negative panel ('clean' samples and disease-specific or blood factor-specific samples).

An overview of the sample collection and characterization process can be found in the methods manuals developed for this purpose *(17-18)*. Characterization results for each Round 1-4 can be found on the WHO/WPRO RDT and FIND websites.[2]

In summary, each panel specimen was characterized for:

i) Species by duplicate microscopy (two microscopists) and confirmation by nested PCR of mono-species infection

ii) Antigen concentration, determined by quantitative ELISA for HRP2, pLDH, aldolase

iii) PCR for malaria and confirmatory testing for other pathology in the case of parasite-negative samples

Most samples in the global specimen bank are also characterized according to HRP2 sequence by PCR amplification. This is no longer performed on samples collected after 2009, as accumulated evidence indicates no significant effect on RDT sensitivity *(19)*. All samples have their geographical origin recorded.

[1] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[2] *http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/call_for_testing_round4.htm; http://www.finddiagnostics.org/*

Table 2: Characteristics of *Plasmodium spp.* negative samples

Nature of negative sample[a]	No.
Clean-negative[b]	58
Anti-nuclear antibody positive (sera)	13
Anti-mouse antibody positive (plasma)	3
Rheumatoid factor positive (whole blood and sera)	4
Rapid plasma reagin positive (sera)	5
Chagas' disease antibody positive (plasma)	2
Dengue antibody positive (whole blood sera)	4
Leishmaniasis antibody positive (sera)	5
Schistosomiasis antibody positive (whole blood and sera)	6

[a] Whole blood unless indicated. Sera and plasma samples were reconstituted packed cells

[b] Healthy volunteers with no known current illness or blood abnormality

Panel composition

P. falciparum–cultured parasites panel

Twenty culture-adapted strains of *P. falciparum* of varied geographical origin were selected, including 15 strains with type B HRP2 sequence, three with Type A, and two with Type C HRP2 sequence. All specimens were derived from the CDC culture bank, and diluted in O positive USA donor blood *(17)*.

Figure 4a: Origin of Phase 2 *P. falciparum* wild type (clinical) samples (n=98)

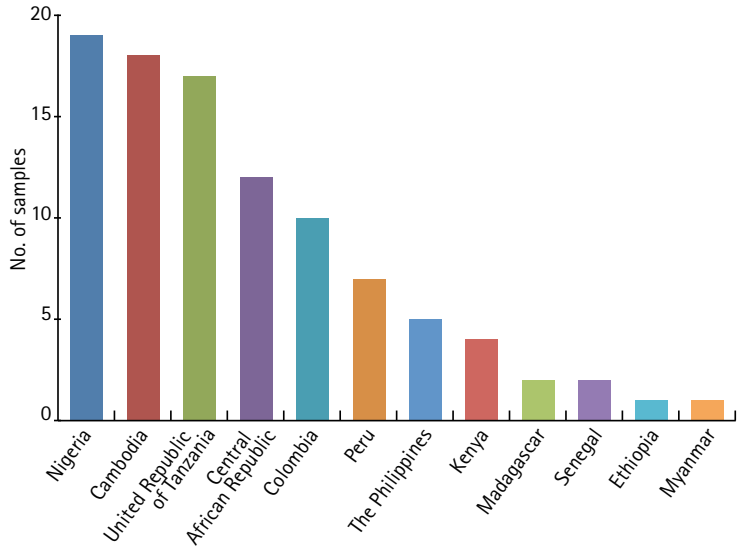
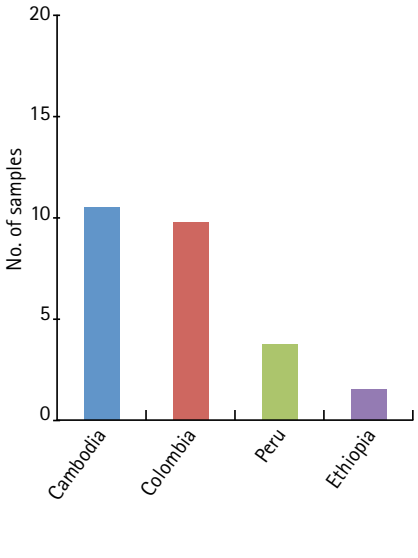


Figure 4b: Origin of Phase 2 *P. vivax* wild type (clinical) samples (n=34)



Wild-type parasite panel

The parasite-positive wild-type (clinical) panel consisted of samples from 98 cases of *P. falciparum* and 34 cases of *P. vivax*, derived from 12 collection sites in Asia, Africa and South America (Figures 2, 4a and 4b).

Samples were collected from febrile patients and processed according to standardized methods designed to preserve target antigen concentration *(18)*. After dilutions and cryo-preservation, samples were transferred to the global bank (WHO Specimen Bank) at CDC for further characterization. The distribution of concentration of HRP2, aldolase and pLDH were determined on a larger sample during the first round of product testing in 2008, and a test panel developed for that round that excluded samples with extremes of high or low antigen concentration. Panels for subsequent rounds, including Round 4, have been maintained within these parameters.

Negative blood samples

The negative panel consisted of 'clean' parasite-negative samples from donor-derived blood obtained in banks or from volunteers in non-endemic (USA) and endemic areas (The Philippines, Madagascar, Senegal, Nigeria and Kenya), having been malaria-negative by microscopy. The panel further contains parasite-negative samples from donors with diseases that may potentially be in the differential diagnoses of malaria, or contain specific blood factors known to be common in the community or known to have the potential to cause false-positive reactions on immunochromatographic tests (Table 2). All negative control samples were confirmed to be free of *Plasmodium* parasites by PCR amplification.

Further details of the culture, wild-type and parasite-negative panels can be found at *http://www.wpro.who.int/NR/rdonlyres/62AA6F12-638E-4C1E-B7CC-10014B2273CA/0/RndFourProdTestEvalPanel_Pub.pdf.*

5.4. RDT registration

The receipt of each shipment of RDTs at the CDC was recorded in a dedicated RDT register. Temperature monitoring devices were offered to manufacturers free of charge, to accompany RDTs shipments to CDC. All RDTs were stored in room temperature at ≤ 25°C immediately and temperature monitors were labelled with receipt date and forwarded for downloading, when applicable.

5.5. Specimen panel registration

All panel specimens were assigned unique identification numbers at the collection sites and stored in aliquots of 50µL at -70°C until the time of testing. All data pertaining to specimen identification, storage location and characterization results are stored in a secure, dedicated database.

5.6. Test phases

The evaluation was divided into two testing phases:

Phase 1 – A screening step to allow the selection of RDTs meeting minimal quality requirements. Products from two lots were evaluated against a panel of 20 culture-derived *P. falciparum* samples at high (2000 parasites/µl) and low (200 parasites/µl) parasite densities. To progress to the full evaluation (Phase 2), a product evaluated in Phase 1 must achieve a minimum 80% panel detection score (PDS) against the 2000 parasites/µl samples (Figure 6).

Phase 2 – Products from two lots were evaluated against a panel of diluted clinical blood samples containing wild-type parasites and a parasite-negative panel, evaluated for heat (thermal) stability, and assessed for ease-of-use.

a. The mixed parasite-positive and parasite-negative panel was comprised of 98 *P. falciparum*, 34 *P. vivax* at two parasite densities (200 parasites/µl and 2000 (or 5000)[1] parasites/µl), and 100 parasite-negative controls.

b. Heat stability evaluation: Baseline testing of 15 RDTs from each of two lots against a single culture-derived *P. falciparum* isolate (Nigeria XII strain, Pf HRP2 sequence type B with a typical antigen concentration) at 200 parasites/µl and 5 RDTs from each lot at 2000 parasites/µl, and 4 RDTs from each lot against a negative sample. This procedure was repeated after RDTs were maintained for 60 days at 4°C, 35°C and 45°C at 75% humidity.

c. Ease-of-use assessment: After becoming familiar with the test device, technicians jointly described the test for blood safety characteristics, quality of instructions, number of timed steps and total time to result, using a standard reference guide *(17)*.

5.7. Performing rapid tests

All RDTs were brought to room temperature prior to first use. Desiccant was inspected for colour changes and products were discarded if they were present. RDTs were labelled with sample identification number, dilution, and the date when test was performed. Performance of rapid tests was in accordance with manufacturer's instructions, with the exception that blood transfer was carried out by micro-pipette from the sample tube. The result was recorded by a technician at the minimum specified reading time. A second technician re-read the result within 1 hour for internal monitoring purposes and for information for manufacturers. Technicians were rotated, and blinded to sample type and to each other's results during Phase 2. Annexes 1 and 2 contain a descriptive and illustrated summary of the test characteristics, steps and guide to interpretation of results.

[1] Five (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

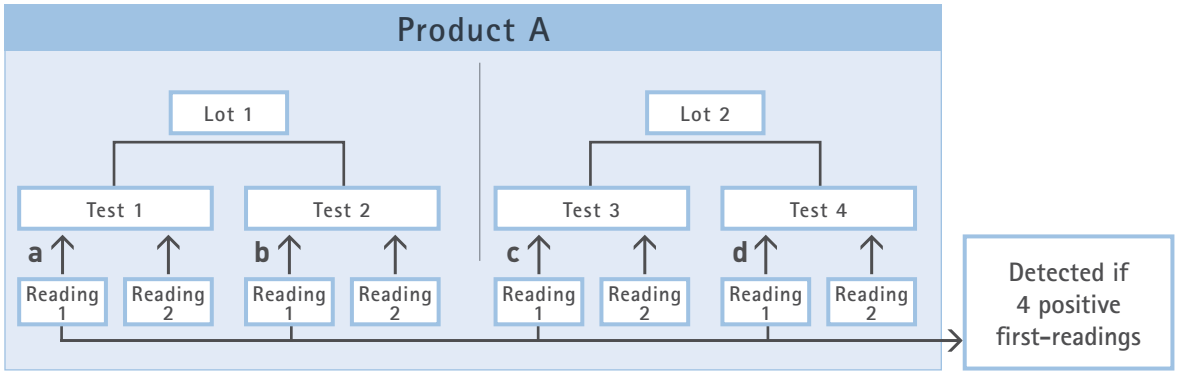
5.8. Interpretation of results

Results of control and test lines were recorded as negative or positive by each technician. Each test was read against a standard colour chart and the band intensity graded as 0 (no visible band), 1, 2, 3 or 4. If the control line is recorded as absent by either technician, the test is recorded as invalid.

Figures 5 and 6 illustrate the testing sequence at low and high parasite densities.

Figure 5: Testing procedure and calculation of 'panel detection score' and band intensity for Product A against a sample density of 200 parasites/µl

The first reading was at the minimum time specified by the manufacturer; the second reading was up to one hour later[a]. A sample is considered detected only if all first test readings, from both lots, are positive ie. Readings a, b, c and d must be positive.

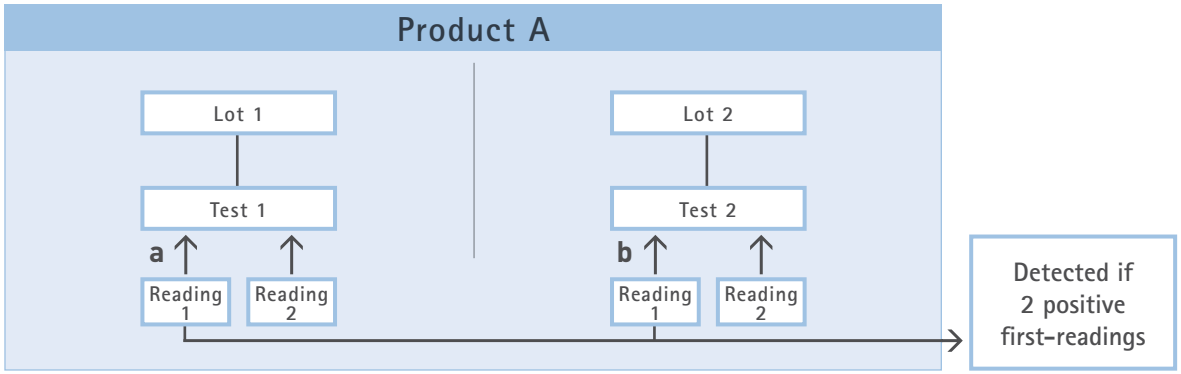


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[a] second reading results are for internal use only

Figure 6: Testing procedure and calculation of 'panel detection score' and band intensity for Product A against a sample density of 2000 parasites/µl

The first reading was at the minimum time specified by the manufacturer; the second reading was up to one hour later[a]. A sample is considered detected only if all first test readings, from both lots, are positive ie. Readings a and b must be positive.



Based on positive results of first test reading (2 tests per lot), in each lot, the mean band intensity score =a+b/2

[a] second reading results are for internal use only

6. DATA MANAGEMENT

The receipt of products was hand recorded in a RDT register at the CDC as per Standard Operating Procedures (SOPs). Data associated with specimen collection and characterization was recorded first on hard copy report forms as per the SOPs at the collection sites (Figure 2), HTD (ELISA results) and CDC (PCR results) and then entered directly into Excel followed by importation into a specially developed database.

The results of the product panel testing and heat stability testing conducted at the CDC were recorded on report forms by each technician individually, as per the SOP. These results were double-data entered, and analysed for discrepancies.

All source documents and electronic records of study data are maintained in secure storage until the conclusion of the evaluation, data analysis and report publication.

Individual product testing reports were distributed to manufacturers' on 3 September 2012, for a 60 day review period prior to publication of the final report. Raw data were made to manufacturers available upon request.

7. QUALITY ASSURANCE

Product testing follows SOPs developed through prior testing experience and are based on recommendations of expert consultations, with minor modifications made on suggestion by the Steering Committee prior to Round 4 *(17)*. In particular, changes in the SOPs from the previous rounds include an increase in the number of RDTs tested against 200 parasites/µL at each stage of stability testing from 10 to 15, while RDTs tested at 2000 parasites/µL were reduced from 10 to 5. Overall, the quality of critical steps was controlled, as follows:

i) Quality of the malaria RDTs and their use:

All RDTs were stored in a controlled environment at room temperatures ≤ 25°C; the pouch was opened and desiccant checked immediately before use; manufacturer instructions were followed with the exception of use of the blood transfer device provided by the manufacturer (a micropipette was used to ensure correct blood volume).

A temperature-monitoring device was offered to be included with the RDTs for shipment to the testing site (CDC). Logs were analysed for any temperatures below or above manufacturers recommended storage conditions.

ii) Quality and objectivity of the RDT reading results:

Results were read in good lighting by trained technicians tested for visual acuity, and doubly entered into the database. Technicians were rotated. Readings of a second technician were used for internal monitoring purposes, and summarized results reviewed in detail and potential discrepancies identified and cross-checked against source laboratory report forms.

All wild-type parasite samples were randomized with parasite-negative samples and re-labelled for blinded reading of the RDT results.

iii) Quality of the WHO Specimen Bank samples:

SOPs were established for the preparation of all specimen bank samples *(18)*. Culture lines of parasites and wild-type samples were selected taking into account previous evidence and data from specifically conducted studies. All diluted parasite samples were stored and transported at -70°C, and were used only once within 8 hours of thawing.

iv) Quality of the product testing site:

The Division of Parasitic Diseases and Malaria (DPDM), Center for Global Health, CDC, is the major operating component of the Department of Health and Human Services (HHS) of the USA that deals with malaria control and prevention. Laboratories within DPDM hold Clinical Laboratory Improvement Amendments (CLIA) accreditation and are monitored by an internal quality management systems (QMS) program.

8. ETHICAL CONSIDERATIONS

Each specimen collection site obtained approval from a WHO Research Ethics Review Committee and/or local institutional review board for specimen collection, transport and archiving of blood samples for the purpose of product testing, lot testing and quality assurance procedures.

9. DATA ANALYSIS

9.1. Measures of parasite detection: panel detection score and positivity rates

Malaria RDTs detect parasite-derived antigen. The relationship of the concentration of antigen available from the blood sample (after lysis of red cells and parasites) to the peripheral parasite density varies highly due to a series of host and parasite factors. In addition, the population frequency of specific factors that can result in false-positive results may vary. Therefore, field sensitivity and specificity of an RDT may change in different epidemiological situations. The evaluation reported here does not predict sensitivity or specificity in a given field situation. It reports comparative detection of target antigens and false-positive rates of RDTs against a standardized panel, in a controlled, repeatable manner. As the panel is developed to be a close approximation of field samples, the comparative detection rates between products are expected to be reflected by similar comparative detection rates in the field. As the panel is designed to include a large number of samples close to the limits of detection of RDTs (200 parasites/µl), the panel is likely to discriminate more clearly than a field trial. It follows that in some settings, such as where parasite density is very high, differences in the panel detection score (PDS) and positivity rates between tests observed against the WHO evaluation panel may not be observed in patient populations, or may be much smaller. Furthermore, where parasite densities are very low, detection rates may be lower than those reported here.

Referring to Figure 5, a product must return four positive test results at the manufacturers' recommended minimum reading time (two from Lot One, two from Lot Two at the initial reading time) when tested against a parasite density of 200 parasites/µl, to contribute to its PDS. When tested against 2000 or 5000 parasites/µl (Figure 6) the product must return two positive tests at the manufacturers' recommended minimum reading time (one from each lot). Thus, the PDS is a measure of inter-test and inter-lot consistency, as well as the ability to detect antigen. The PDS for *P. falciparum* indicates an RDT result confirming the presence of *P. falciparum,* when tested against cultured and wild-type *P. falciparum* samples, while the non-*P. falciparum* PDS (*P. vivax* detection in this Report) indicates *Plasmodium*-positive/*P. falciparum*-negative results when tested on wild-type *P. vivax* samples.

The positivity rate is the percentage of all tests of a particular product that returned a positive test result, at the manufacturers' recommended minimum reading time, when tested against a *P. falciparum* or *P. vivax* sample.

9.2. False-positive results

False-positive results are analysed and reported as two separate groups; those that had incorrect species identification,

and those that returned a positive result for samples not containing *Plasmodium* spp. parasites. Specifically, the false-positive rate is the percentage of all tests of a particular product that returned a positive test result when it shouldn't have, based on results at the manufacturers recommended minimum reading time.

9.2.1. Incorrect species identification

A test is considered as returning an incorrect species result if a positive *P. falciparum* test line appears upon testing against a sample containing non-*P. falciparum (P. vivax)* parasites. *P. falciparum* samples resulting in only a visible pan-specific (or non-*P. falciparum*-specific) test line on combination tests are also considered to be false-positives.

9.2.2. False-positives from *Plasmodium*-negative samples

Any test that produces a positive reading to samples with no *Plasmodium* parasites is considered a false-positive. In Phase 2, parasite-negative samples consist of clean-negative samples and also samples containing other infectious agents (e.g. dengue, leishmania, Chagas) and immunological factors (e.g. rheumatoid factor, anti-nuclear antibodies, anti-mouse antibodies) (Table 2).

9.3. Band intensity

All positive test results were recorded according to the band intensity against a standard reference chart, matched closely to line colour. Based on the first reader results, the distribution of band intensity results is presented as the mean band intensity of positive results. In addition, the intensity was expressed for each possible result (0, 1, 2, 3 or 4) as the percentage recorded at that level[1].

9.4. Lot agreement

Disagreement between test lots is calculated from the number of samples that returned a positive result **on both RDTs** tested in that lot against parasite-positive samples at 200 parasites/µl, and on the single RDT from each lot tested against samples at 2000 (or 5000) parasites/µl. Thus, high inter-lot agreement indicates consistency in detecting malaria parasites. Where one test was invalid and the other positive, positive agreement was recorded.

9.5. Invalid tests

These are the total number of tests that were deemed invalid during testing of both lots, using samples at 200 parasites/µl and 2000 (or 5000) parasites/µl.

9.6. Heat (thermal) stability

The results of heat stability testing are reported as the number of positive tests returned based on either Reading 1 or Reading 2 from two lots at each parasite density (maximum score 30 against 200 parasites/µl samples; 10 against 2000 parasites/µl samples)[2] and mean band intensity (for positive tests only based on either Reading 1 or 2) at baseline and after lots were stored at 4°C, 35°C and 45°C for two months against one cultured *P. falciparum* parasite sample at 200 and 2000 parasites/µl.

[1] A standard intensity comparison chart is used which allows matching to the closest of four common colour variants of labelled antibodies used on RDTs, each at four levels of intensity.

[2] Fifteen tests per lot against 200 parasites/µl samples and 5 tests per lot against 2000 parasites/ µl samples. Invalid results were excluded from analysis.

10. LABORATORY VERSUS FIELD-BASED MALARIA RDT EVALUATIONS

Despite the strengths of the product testing programme, the evaluation is not completely analogous to field testing of malaria RDTs. In order to compose a panel that could be reproducibly used to evaluate RDTs, blood samples were diluted, frozen and stored below –70°C. Blood that has undergone a freeze thaw process and is therefore lysed may not have exactly the same characteristics as fresh blood. A further variation from field equivalence is the use of a micro-pipette to supply blood to the RDT device rather than the blood transfer device provided by the manufacturer. This was necessary because blood is collected from a cryo-tube rather than a finger-prick, and the blood transfer devices provided with a particular product can vary (*20*). This technique also ensured consistency of testing by reducing the likelihood of operator error. All samples in the panel used for the evaluation are prepared from parasites that express HRP2. The results will therefore not be predictive of field trial results involving parasite populations with significant levels of HRP2 deletion *(21)*.

Field trials have a place in product selection, particularly in determining which of a short-list of products is most appropriate for the technicians and situation of its intended use by a programme (e.g. ease-of-use characteristics). Such trials should have carefully defined objectives and procedures designed to achieve these. Trials to determine the likely field sensitivity and specificity of a product also have a place, but require large sample sizes and populations with low parasite densities to determine significant differences between well-performing products, they need to be tightly controlled, and are therefore expensive. They do not allow comparison of a large number of products. WHO has produced recommendations on good practice for malaria field trials which should be followed to improve the repeatability and quality of results *(22)*.

11. RESULTS

11.1. Summary

Round 4 of WHO Malaria RDT Product Testing, reports results for 48[1] products evaluated against *P. falciparum* culture samples, and for 46 of these products that proceeded to evaluation against wild-type samples collected from parasitaemic patients from three continents and a large panel of parasite-negative samples. Heat stability was assessed at temperatures commonly encountered in malaria endemic countries. Thirteen research institutes have been engaged in either sample collection or sample characterization to establish the evaluation panels. Between June 2011 and May 2012 approximately 56,000 tests were performed at the CDC.

The results of the evaluation reveal the following key outcomes:

i) The overall range of results including PDS, positivity rate, false-positive rates and heat stability, were similar to those reported in Rounds 1–3 (*3-5*) . There has been a gradual increase in median PDS for *P. falciparum* at low parasite densities across the rounds. The change in PDS for *P. vivax* at low densities has been less consistent although the median for Round 4 (61.8) was higher than in the previous round (51.4).

ii) A number of RDTs 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, adding to the number of available well-performing tests included in Rounds 1, 2 and 3.

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

iv) Again *P. falciparum* tests targeting HRP2 antigen demonstrated the highest PDS for *P. falciparum*. The two tests targeting pf-pLDH for *P. falciparum* detection did not pass Phase 1 (<80% PDS for *P. falciparum* at 2000 parasites/µl). Furthermore, of those tests with both a HRP2 and pf-pLDH test line, the PDS based on the HRP2 line was substantially better than PDS based on the pf-pLDH line[2].

v) Several combination tests achieved PDS in the high part of the range for both *P. falciparum* and *P. vivax*.

vi) Test performance sometimes varied between lots of some products.

Tables 3 and 4 summarize the performance of malaria RDTs against *P. falciparum* cultured parasites and blood containing wild-type *P. falciparum* and *P. vivax* parasites and *Plasmodium* spp. negative samples. It is important to note that although, results for 48 products are reported, only 44 were actually tested. The four products listed that were not tested are re-labelled/re-branded versions of the same product that was evaluated[3]. All six products are manufactured at the same location and under the same conditions so the numbers of products discussed below reflect the 44 products that were actually tested and the four co-listed products that are listed with the same results. The data are colour coded according to arbitrary categories, to ease the interpretation of results, and these do not imply limits of acceptable or unacceptable performance. Detailed information pertaining to product testing Phase 1 and Phase 2 results is included in Annex 3 and Annex 4, respectively. A graphical representation of this data follows in Figures 7–15.

[1] This includes four products that were joint listed which were not evaluated at the CDC , refer to footnote 3 on this page for product-specific details

[2] AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device (MFV-124F);SD BIOLINE Malaria Ag Pf/ Pf/ Pv (05FK100)

[3] ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO and Medisensor Malaria HRP2/pLDH (Pf/PV) COMBO are rebranded/identical to CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO (G0161) and ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO and Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO are rebranded/identical to CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO (G0171)

Table 3: Summary Phase 1 performance of 48 malaria RDTs against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite densities (parasites/µl)

Product	Catalogue number	Manufacturer	Panel Detection Score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200 parasites/µl	2000 parasites/µl	200 parasites/µl (n=80)	2000 parasites/µl (n=40)	
Pf only							
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	20.0	95.0	NA	NA	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	100.0	100.0	NA	NA	0.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	100.0	100.0	NA	NA	0.0
ICT MALARIA P.F.	ML04	ICT INTERNATIONAL	0.0	75.0	NA	NA	0.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	60.0	100.0	NA	NA	0.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	80.0	100.0	NA	NA	0.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	NA	NA	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	100.0	100.0	NA	NA	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	85.0	100.0	NA	NA	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	80.0	95.0	NA	NA	0.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	85.0	100.0	NA	NA	0.0
Pf and Pan							
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	95.0	100.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Devicec	MFV-124F	AZOG, INC.	60.0	100.0	1.3	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	85.0	100.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	85.0	100.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	0.0	0.0	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	85.0	100.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	95.0	100.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	45.0	90.0	6.3	2.5	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	65.0	100.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	80.0	100.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	85.0	100.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	100.0	100.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	65.0	100.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	75.0	100.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	90.0	100.0	0.0	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	100.0	100.0	0.0	0 (39)	0.8
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	95.0	100.0	2.5 (79)	0 (39)	1.7
Pf and Pv							
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	85.0	100.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	95.0	100.0	0.0	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	95.0	95.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	95.0	100.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	85.0	100.0	0.0	2.6 (39)	0.8
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	45.0	100.0	10.0	12.8 (39)	0.8

Table 3 *(continued)*

Product	Catalogue number	Manufacturer	Panel Detection Score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200 parasites/µl	2000 parasites/µl	200 parasites/µl (n=80)	2000 parasites/µl (n=40)	
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	75.0	100.0	1.3 (77)	0.0	2.5
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	85.0	100.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	95.0	100.0	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	60.0	95.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	70.0	100.0	5.0	2.5	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	85.0	100.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	95.0	100.0	0.0	0.0	0.0
RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/PV TEST	MAL-PFV-0207	Hema Diagnostic Systems, LLC	0.0	0.0	1.3 (79)	2.6 (39)	1.7
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	100.0	100.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pvc	05FK100	Standard Diagnostics Inc.	95.0	100.0	1.3	5.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	80.0	95.0	55.0	70.0	0.0
Pan only							
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	55.0	100.0	NA	NA	0.0

NA, not applicable

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

[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] Pan or Pv line only positive indicates a false-positive non *P. falciparum* infection

[c] 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 for 05Fk100 (Standard Diagnostics Inc) was: pf-pLDH (5% at 200p/µl; 100% at 2000p/µl) and pf-HRP2 (95% at 200p/µl; 100% at 2000p/µl) and for MFV-124F (AZOG, Inc.) was pf-pLDH (0% at 200p/µl; 10% at 2000p/µl) and pf-HRP2 (60% at 200p/µl; 90% at 2000p/µl)

Detection rate (%)	≥95	85-94	50-84	< 50
False-positive rate (%)	<2	2-5	6 -10	>10
Invalid rate (%)	<1% of tests conducted	1-2% of tests conducted	2-5% of tests conducted	>5% of tests conducted

Table 4: Summary Phase 2 performance of 46 malaria RDTs against wild type (clinical) *P. falciparum* and *P. vivax* samples at low (200) and high (2000[a]) parasite density (parasites/µl) and *Plasmodium* spp. negative samples

Product	Catalogue number	Manufacturer	Panel Detection Score[b]				False-positive rates (%)				Total false-positive rates[e] (%)	Invalid rate (%) (n=1192)
			200 parasites/µl		2000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean-negative samples	
							Pf samples	Pv samples	Pf samples	Pv samples		
			Pf samples (n=98)	Pv samples (n=34)	Pf samples (n=98)	Pv samples (n=34)	False-positive non Pf infection[c] (n=392)	False-positive Pf infection[d] (n=136)	False-positive non Pf infection[c] (n=196)	False-positive Pf infection[d] (n=68)	False positive *Plasmodium spp.* Infection (n=232)	
Pf only												
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	99.0	NA	100.0	NA	NA	97.1	NA	95.6	99.1 (231)	0.5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.5	2.2 (231)	0.2
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	61.2	NA	99.0	NA	NA	2.2	NA	14.7	6.0	0.1
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	98.0	NA	NA	1.5	NA	0.0	0.4	0.2
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0.0	NA	1.5	1.3	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	NA	0.0	1.3	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0.0	NA	0.0	0.9	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.9	5.2 (230)	0.7
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	89.8	NA	99.0	NA	NA	0.0	NA	0.0	0.4 (231)	0.2
Pf and Pan												
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[f]	MFV-124F	AZOG, INC.	62.2	0.0	98.0	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	100.0	29.4	0.0	33.8	0.0	42.7	32.2 (230)	0.3
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	76.5	11.8	99.0	94.1	0.3 (391)	2.2	0.0	0.0	3.5 (231)	0.3
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	0.0	100.0	0.0	0.0	99.3	0.0	98.5	97.8	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	76.5	5.9	99.0	88.2	0.5	0.7	0.0 (195)	1.5	0.4	0.1
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	94.9	61.8	100.0	85.3	0.0	2.2	0.0	5.9	1.3	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	63.3	2.9	100.0	97.1	0.3	0.7	0.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	39.8	2.9	94.9	85.3	0.0	0.0 (135)	0.0	0.0	0.0	0.1
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	84.7	0.0	100.0	76.5	0.0 (391)	2.2	0.0	1.5	1.3	0.1
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	99.0	0.0	0.0 (391)	0.0	0.0	1.5	0.9	0.1
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	74.5	88.2	98.0	97.1	0.0	0.0	0.0	1.5	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	84.7	61.8	99.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	76.5	82.4	100.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	99.0	26.5	100.0	23.5	0.0 (391)	30.2	0.0	50.0	26.7	0.3
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	90.8	94.1	100.0	100.0	1.0 (385)	0.0 (130)	0.0 (195)	0.0 (67)	1.3 (226)	2.8
Pf and Pv												

Table 4 *(continued)*

Product	Catalogue number	Manufacturer	Panel Detection Score[b]				False-positive rates (%)				Total false-positive rates[e] (%)	Invalid rate (%) (n=1192)
			200 parasites/µl		2000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean-negative samples	
			Pf samples (n=98)	Pv samples (n=34)	Pf samples (n=98)	Pv samples (n=34)	Pf samples	Pv samples	Pf samples	Pv samples		
							False-positive non Pf infection[c] (n=392)	False-positive Pf infection[d] (n=136)	False-positive non Pf infection[c] (n=196)	False-positive Pf infection[d] (n=68)	False positive *Plasmodium spp.* Infection (n=232)	
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	98.0	88.2	100.0	100.0	0.8	2.9	0.0	2.9	7.3	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	100.0	94.1	0.3 (391)	0.0	0.5	0.0	0.4	0.1
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	100.0	91.2	0.0	0.0	0.5	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	100.0	100.0	0.5	0.7	0.5	1.5	1.3	0.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.8	0.0	94.9	5.9	0.8	0.7	0.5	0.0	0.9	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	92.9	26.5	0.5	0.0 (135)	3.1 (195)	1.5	0.0 (230)	0.5
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	50.0	0.0	95.9	91.2	0.0	2.9	0.0	1.5	1.3	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	79.6	100.0	100.0	100.0	1.5	0.0	2.0	0.0	1.3	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	100.0	100.0	0.0	0.7	0.0	1.5	4.3	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[f]	05FK100	Standard Diagnostics Inc.	96.9	97.1	100.0	100.0	0.3	0.0	0.5	0.0	2.2	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	99.0	100.0	13.3	27.4 (135)	16.0 (194)	19.4 (67)	32.0 (231)	0.5
Pan only												
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0.0	99.0	55.9	NA	NA	NA	NA	2.2	0.2

NA, not applicable

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

[a] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive

[c] For combination tests, Pan or Pv line, only, positive indicates a false-positive non *P. falciparum* infection

[d] Pf line positive indicates a false-positive *P. falciparum* infection

[e] The total number of times a positive result for malaria was generated when it should not have been

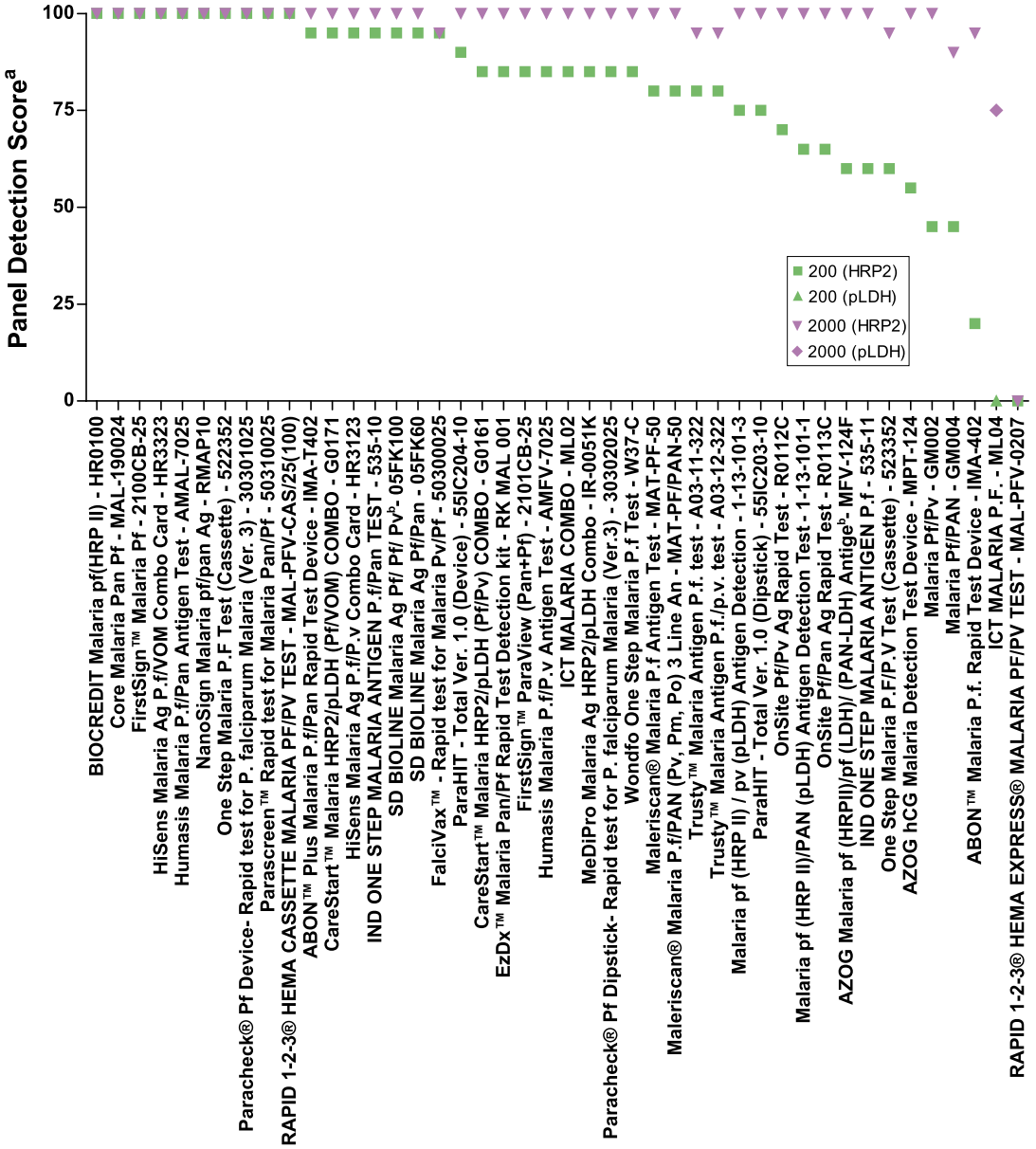
[f] PDS presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH). *P. falciparum* PDS based on individual test lines for 05Fk100 (Standard Diagnostics Inc) was: pf-pLDH (25.5% at 200p/µl; 96.9% at 2000p/µl) and pf-HRP2 (96.9% at 200p/µl; 100% at 2000p/µl) and for MFV-124F (AZOG, Inc.) was pf-pLDH (3.1% at 200p/µl; 37.8% at 2000p/µl) and pf-HRP2 (62.2% at 200p/µl; 98% at 2000p/µl)

Detection rate (%)	≥95	85-94	50-84	< 50
False-positive rate (%)	<2	2-5	6 -10	>10
Invalid rate (%)	<1% of tests conducted	1-2% of tests conducted	2-5% of tests conducted	>5% of tests conducted

11.2. Phase 1 - *P. falciparum* culture panel

The majority of tests (94%) consistently detected ≥ 95% of *P. falciparum* cultured parasites at high parasite densities (2000 (or 5000) parasites/µl); however, the panel detection score was highly variable (0-100%) at low parasite densities (200 parasites/µl). At low parasite densities, the products with the highest PDS targeted HRP2 (Figure 7). Two products had a PDS < 80% on high parasite density samples and therefore, did not proceed onto Phase 2.

Figure 7: Phase 1 *P. falciparum* panel detection score of malaria RDTs at low (200) and high (2000) parasite densities (parasites/µl) according to target antigen type (HRP2 or pLDH)



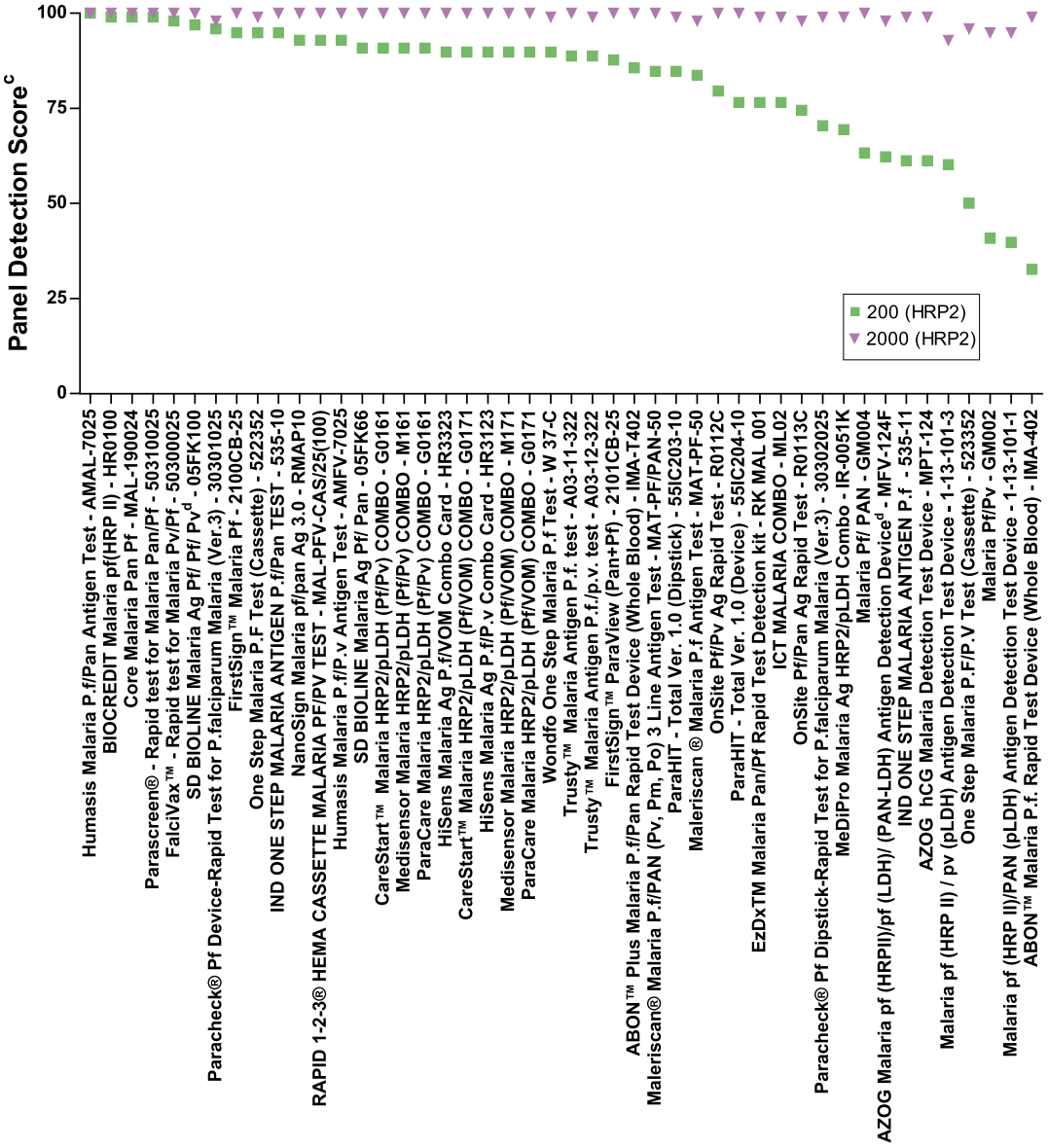
[a] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive;
[b] Refer to Table 3 for individual HRP2 and pf-pLDH test line PDS.

11.3. Phase 2 - Wild-type *P. falciparum* and *P. vivax* and *Plasmodium* spp. negative samples

11.3.1. *P. falciparum* detection

All 48 products in Round 4 were designed to detect *P. falciparum*. Compared to the *P. falciparum* cultured parasite panel, *P. falciparum* PDS and positivity rates of wild-type samples were generally higher, reflecting the increased antigen content of wild-type samples. As in Phase 1, the majority of tests (45; 98%) had a panel detection score ≥95% of *P. falciparum* samples at high parasite densities. Seven of the ten products specific for *P. falciparum* alone achieved PDS of ≥75% against low parasite density samples (Figure 8).

Figure 8: Phase 2 *P. falciparum* panel detection score of malaria RDTs at low (200) and high (2000[a]) parasite density (parasites/µl) according to target antigen type (HRP2 or pLDH)[b]



[a] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[b] Phase 2 evaluation panel consisted of 98 clinical blood samples containing wild type *P. falciparum*. RDTs performed = 2 tests x 2 lots at 200 p/µl and 1 test x 2 lots at 2000 p/µl;

[c] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive;

[d] Refer to Table 4 for individual HRP2 and pf-pLDH test line PDS

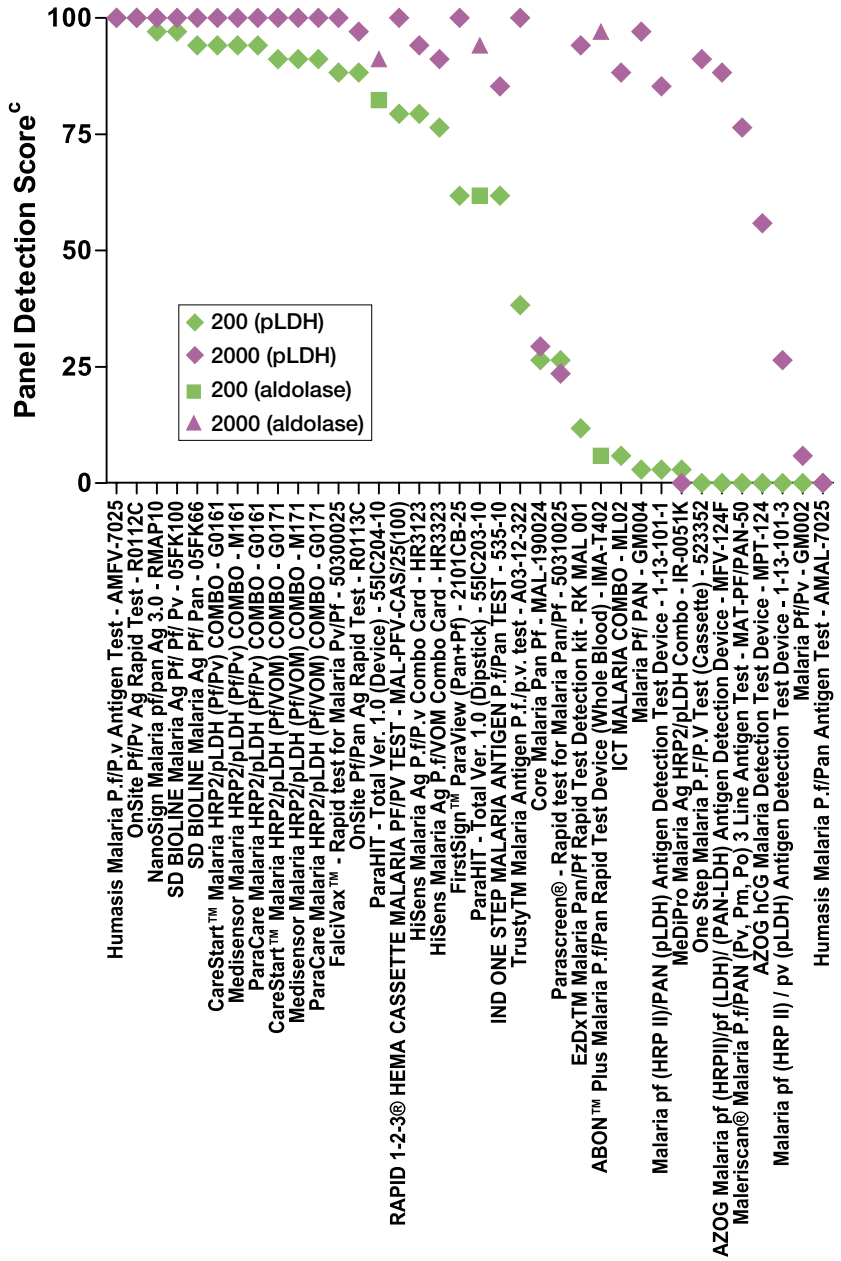
11.3.2. *P. vivax* detection

Figure 9 illustrates, that 28 (78%) of products designed to detect *P. vivax* detected ≥ 75% of the high parasite densities (2000 (or 5000) parasites/µl) consistently, and 17 (47%) achieved the same threshold of PDS against 200 parasite/µL samples. The overall detection of the low parasite density wild-type *P. vivax* samples was lower than that for *P. falciparum*. At low parasite densities (200 parasite/µL), only 11 products had panel detection scores ≥ 90% and 19 products had a PDS of <75%. (Table 4)

11.3.3. Combined detection of *P. falciparum* and *P. vivax*

Considering the 36 pan-specific and combination tests, 17 (47%) had a PDS of ≥75% for both *P. falciparum* and *P. vivax* at the low parasite density (200 parasites/µl) (Table 4). Several performed well at high parasite densities. The single pan-specific only test had a 0% PDS for *P. vivax* at the low parasite densities.

Figure 9: Phase 2 *P. vivax* panel detection score of malaria RDTs at low (200) and high (2000[a]) parasite densities (parasites/µl) according to target antigen type (aldolase, pLDH)[b]



[a] 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl;

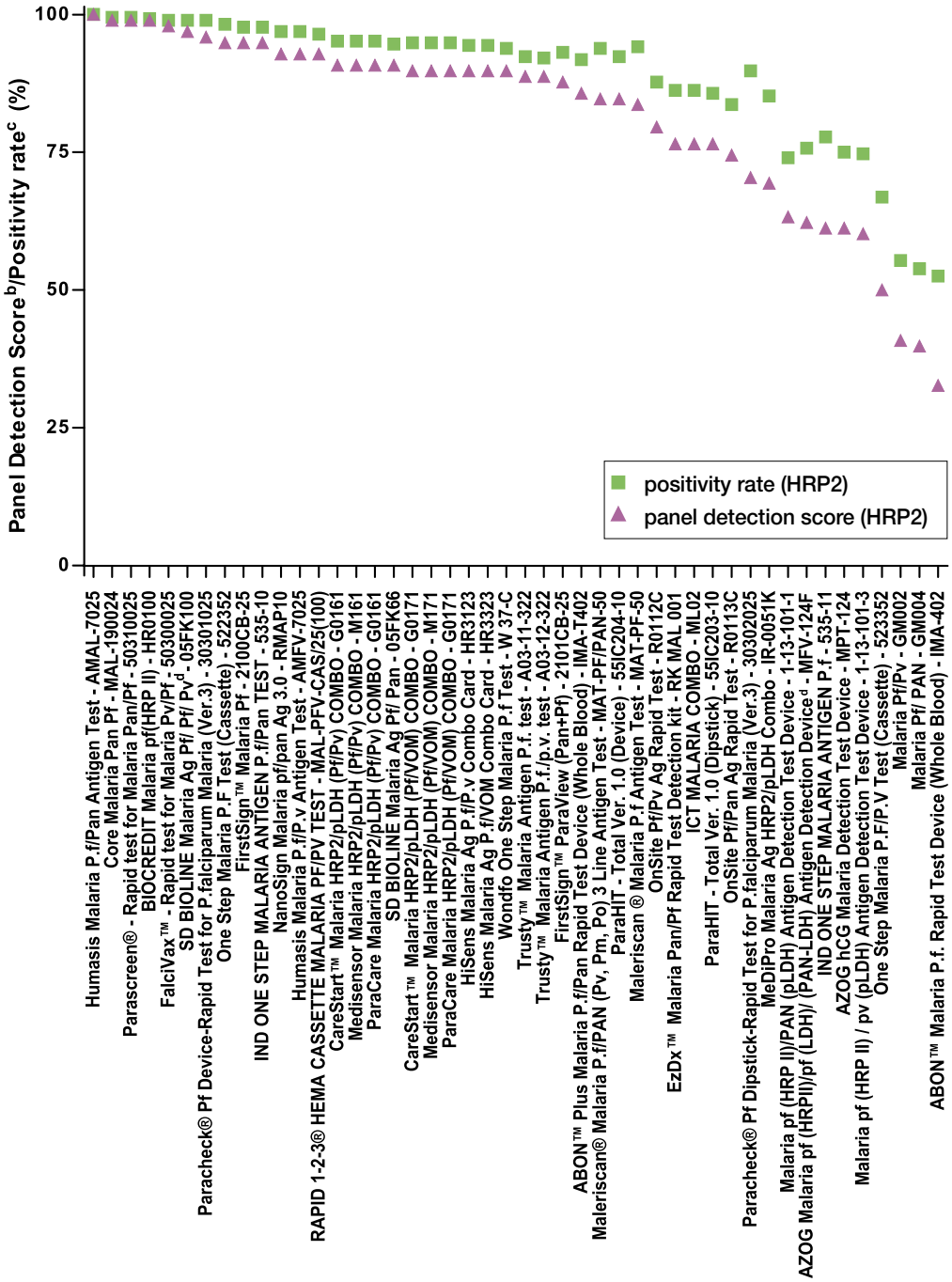
[b] Phase 2 evaluation panel consisted of 34 clinical blood samples containing wild type *P. vivax*; RDTs performed = 2 tests x 2 lots at 200 p/µl and 1 test x 2 lots at 2000 p/µl;

[c] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive

11.3.4. *P. falciparum* and *P. vivax* positivity rate

In addition to the PDS, the positivity rate was also measured. This puts aside test and lot differences captured in the PDS and measures the total number of times a test returned a positive result. As expected, positivity rates were higher than PDS but mirrored PDS against wild-type *P. falciparum* and *P. vivax* samples (Figures 10 and 11).

Figure 10: Phase 2 *P. falciparum* panel detection score PDS and positivity rate at 200 parasites/µl[a]



[a] Phase 2 evaluation panel consisted of 98 clinical blood samples containing wild type *P. falciparum*. RDTs performed = 2 tests x 2 lots at 200 p/µl and 1 test x 2 lots at 2000 p/µl;

[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive;

[c] The total number of times a test returned a positive result;

[d] Refer to Table 4 for individual PDS based on HRP2 and pf-pLDH test lines; for positivity rate (PR) at 200 p/µl: 05Fk100 (Standard Diagnostics Inc) was: pf-pLDH=45.2% and pf-HRP2=99% and for MFV-124F (AZOG, Inc.) PR at 200 p/µl was pf-pLDH=9.2% and pf-HRP2 75.5%

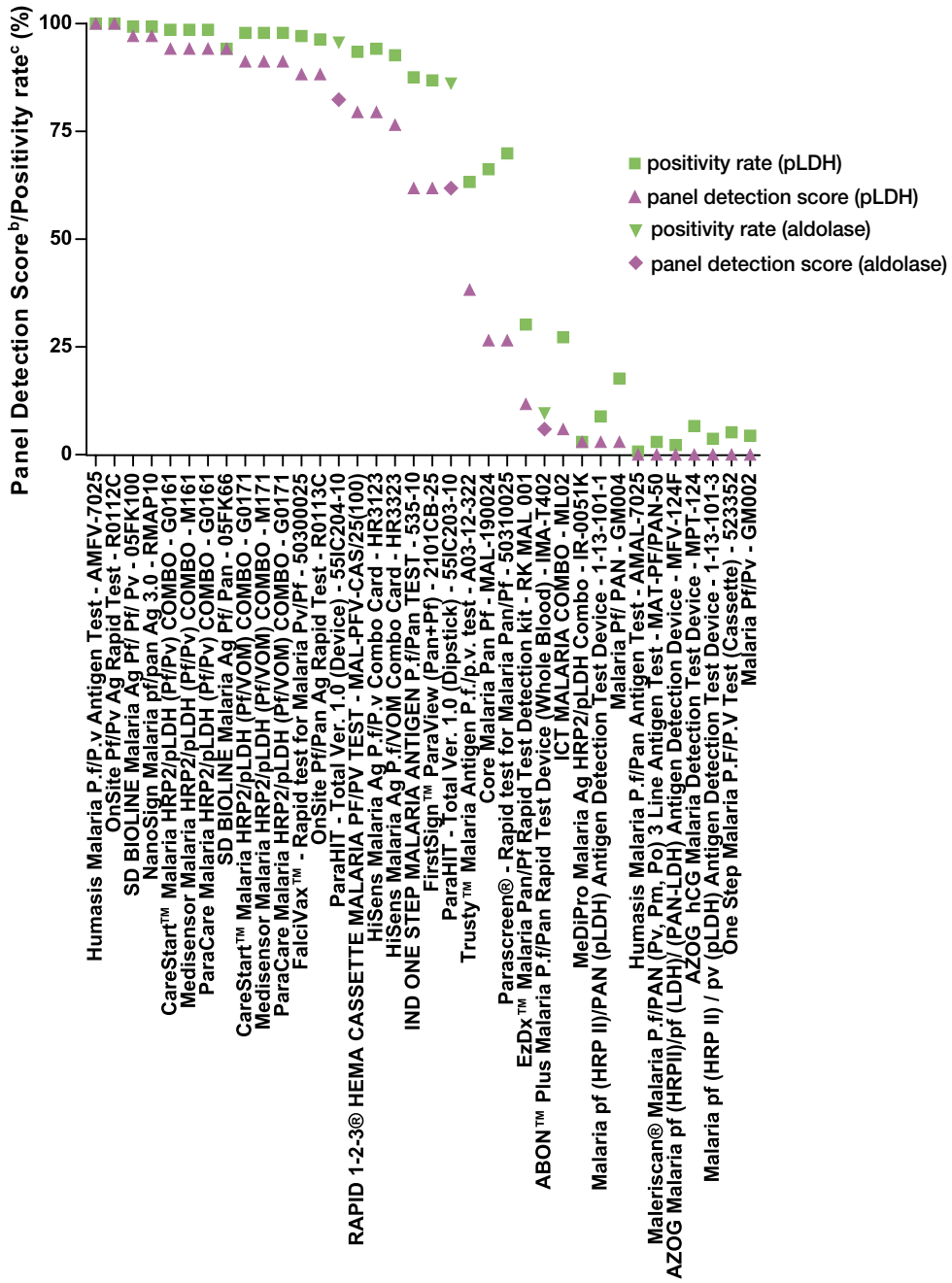
11.3.5. Band intensity

Although RDTs are not quantitative, technicians did grade positive results according to a standard colour chart and mean band intensity (for positive results) was calculated (Annex 4 - Tables A4.2, A4.3). There was a positive correlation between panel detection score and band intensity (Spearman rank correlation, r=0.83, P<0.001).

11.3.6. False-positive rates

Overall false-positive rates were low, with only five tests having rates >10% on clean-negative samples, on any test line (Figures 12, 13). These same five tests also had high false-positive (FP) rates with samples containing other pathogens and immunological abnormalities. A few tests with low false-positive rates on clean-negative samples returned false-positive rates (range 8.3%–50%) against samples from

Figure 11: Phase 2 *P. vivax* panel detection score and positivity rate at 200 parasites/µl[a]



[a] Phase 2 evaluation panel consisted of 34 clinical blood samples containing wild type P. vivax; . RDTs performed = 2 tests x 2 lots at 200 p/µl and 1 test x 2 lots at 2000 p/µl;

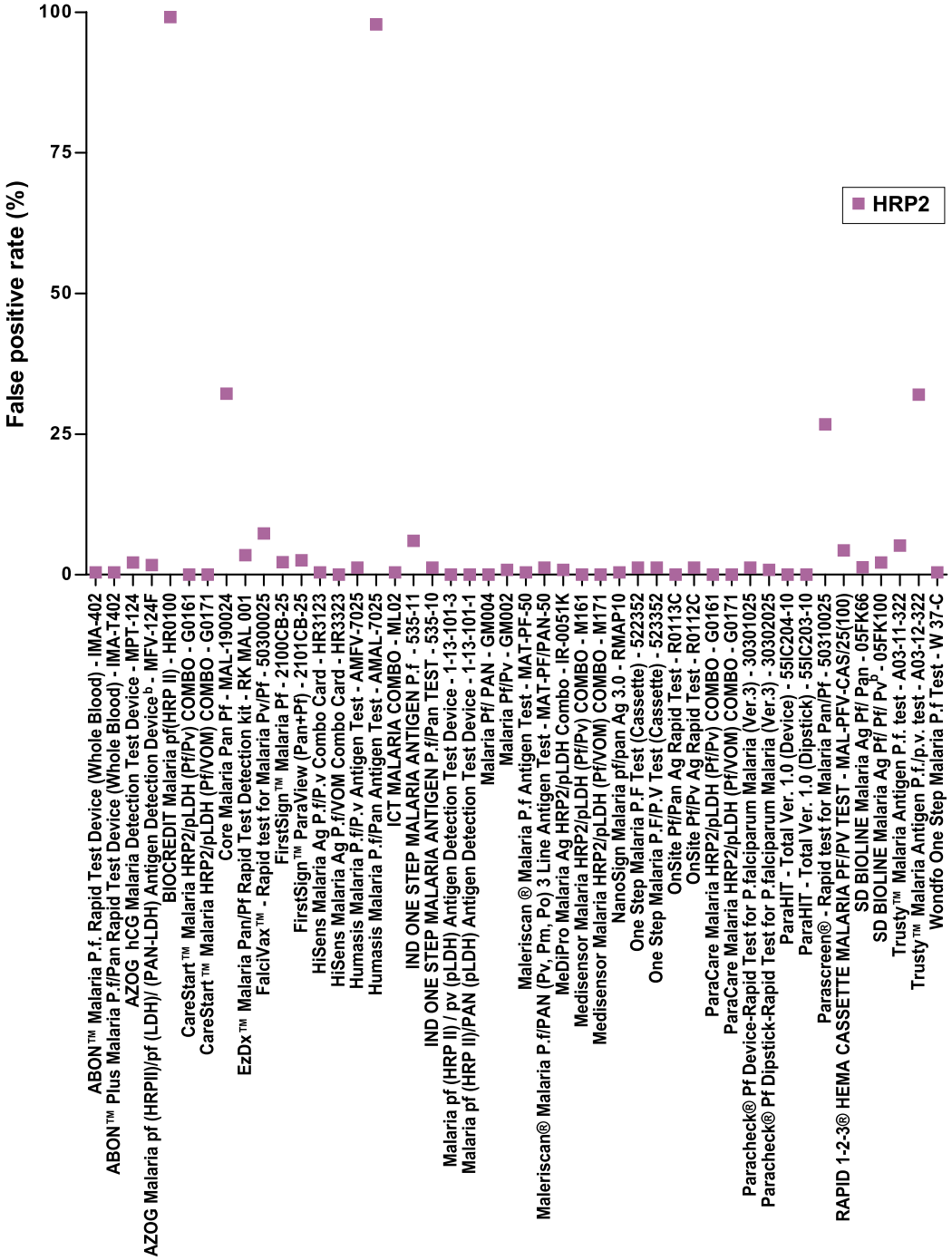
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive;

[c] The total number of times a test returned a positive result

patients with other blood pathogens, particularly for dengue and leishmaniasis and for immunological blood abnormalities (FP rate range 3.9%–66.7%), including RPR, rheumatoid factor, anti-DNA antibody and human anti-mouse antibody samples. However, sample sizes were small. For detailed information regarding the blood abnormality or pathogen that generated false-positive results for a specific product refer to Annex 4 (Tables A4.8, A4.9).

Importantly, there was no clear trend of higher false-positive rates for tests with higher PDS, indicating that there was not a clear trade-off between sensitivity and specificity of tests at these detection thresholds (Figures 14, 15).

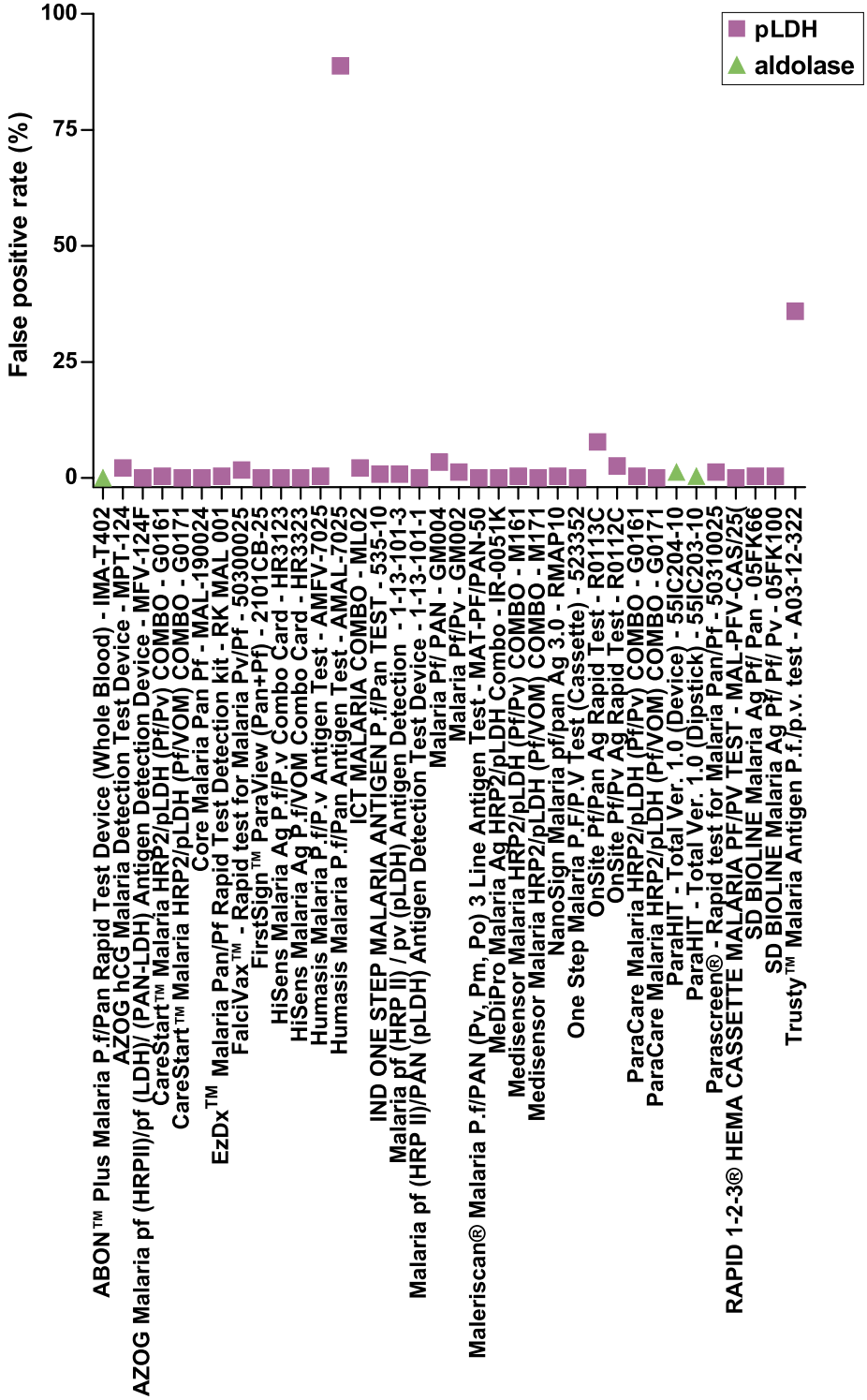
Figure 12: Phase 2 *P. falciparum* (*P. falciparum* test line) false-positive rate against clean-negative samples[a]



[a] Phase 2 evaluation panel included 100 *Plasmodium* spp. negative samples of which 58 were clean-negatives from healthy volunteers with no known current illness or blood abnormality

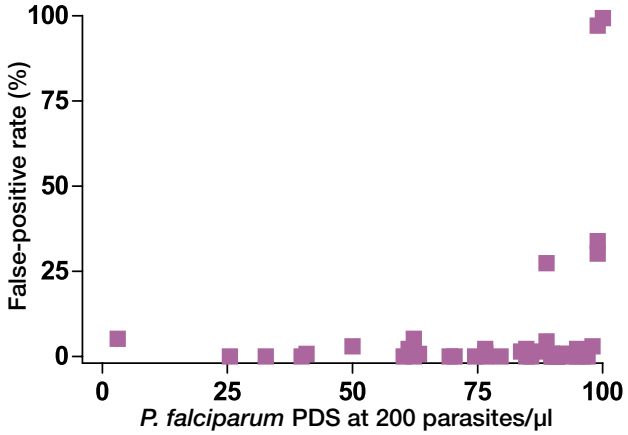
[b] Individual false-positive (FP) rates based on HRP2 and pf-pLDH test lines were: 05Fk100 (Standard Diagnostics Inc): pf-pLDH=0% and pf-HRP2=2.2% and for MFV-124F (AZOG, Inc.) FP was pf-pLDH=1.3% and pf-HRP2=0.4 %

Figure 13: Phase 2 *Plasmodium* spp. (*pan* or *P. vivax*/Pvom test line) false-positive rate against clean-negative samples[a]



[a] Phase 2 evaluation panel included 100 *Plasmodium* spp. negative samples of which 58 were clean-negatives, from healthy volunteers with no known current illness or blood abnormality

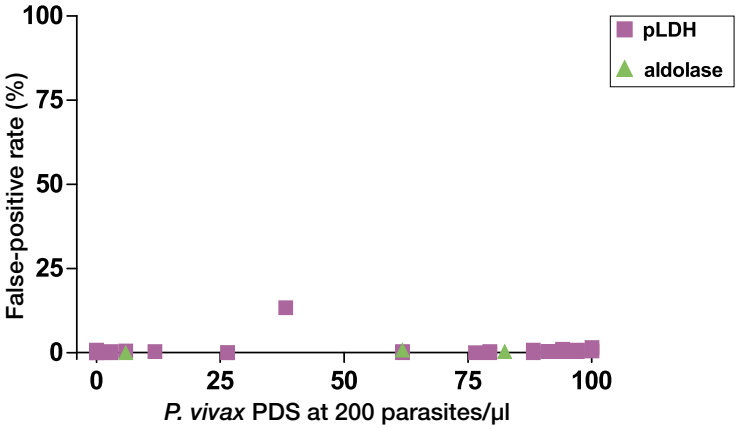
Figure 14: Phase 2 *P. falciparum* false-positive rate[a] versus *P. falciparum* panel detection score[b] at low (200) parasite density (parasites/µl)



[a] False-positive rate is on clean-negatives, only;

[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.

Figure 15: Phase 2 *P. vivax* false-positive rate[a] versus *P. vivax* panel detection score[b] at low (200) parasite density (parasites/µl)



[a] False-positive rate is on clean-negatives, only;

[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.

12. HEAT STABILITY

A single *P. falciparum* culture sample (from the same lot as Round 3) was used as the reference sample for heat stability testing. Variations in baseline performance reflect inter-test variation since the sample at 200 parasites/µl was at the limit of detection of some products.

Several products were stable, meaning that they detected a *P. falciparum* cultured sample the same number of times at baseline and following incubation for two months (75% humidity) at 4°C, 35°C and 45°C. (Table 5). Detailed results are presented in Annex 4 (Tables A4.11-A4.13a) and in Figures 16-23, showing the results of both lots are combined (maximum score 30; 15 tests per lot against 200 parasites/µl; maximum score 10; 5 tests per lot against 2000 parasites/µl).

Overall, products showed greater stability against samples with high (2000 parasites/µl) compared to low (200 parasites/µl) parasite densities, Figures 16, 18, 20, 22 and Figures 17, 19, 21, 23, respectively, as small deteriorations at these high parasite densities will not be apparent. In several cases products which had baseline positivity less than 100% based on the pan-line showed unpredictable variation in positivity rates on subsequent testing after two months, consistent with test lines on the borderline of visibility (i.e. as the 200 parasite/µL culture sample used is near the threshold of detection of many products, a minor change in detection threshold may cause a large apparent change in the recorded result). Some test lines showed a high degree of stability at 35°C but lost the ability to detect antigen after incubation at 45°C. As previously reported, a few products showed an improved performance with incubation (Figures 17, 18, 20, 22, 23). Overall, the stability of pan-pLDH-detecting test lines was much lower than that for HRP2-detecting test lines, for both high and low parasite density samples. The only two products with good reactivity after prolonged storage at 35°C and 45°C had very high false-positive rates for wild-type and parasite-negative sample types .

The summary results of heat/thermal stability testing are presented in Table 5. Note that, as a culture-derived *P. falciparum* sample is used for heat stability testing, it is not possible to provide stability data on test lines that detect only non-*P. falciparum* parasites. Such data, and confirmatory data on the stability of recent production lots of all tests, should be obtained from manufacturers during product selection processes when procuring RDTs (Annex 5a).

Table 5: Heat stability testing results for 46 malaria RDTs 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[c]

Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)		
			200 parasites/µl			200 parasites/µl			2000 parasites/µl			2000 parasites/µl		
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C
			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined		
Pf only														
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	15.0	17.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	30.0	30.0	26.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	30.0	29.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	30.0	30.0	17.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	30.0	29.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Pf and Pan														
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[a]	MFV-124F	AZOG, INC.	29.0	29.0	30.0	1.0	0.0	0.0	10.0	10.0	10.0	2.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b]	MFV-124F	AZOG, INC.	4.0	1.0	2.0	1.0	0.0	0.0	5.0	1.0	5.0	2.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	30.0	30.0	30.0	8.0	24.0	25.0	10.0	10.0	10.0	10.0	10.0	10.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	7.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	29.0	30.0	30.0	0.0	0.0	4.0	10.0	10.0	10.0	10.0	10.0	10.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	30.0	30.0	30.0	23.0	30.0	30.0	10.0	10.0	10.0	10.0	10.0	10.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	29.0	29.0	28.0	1.0	6.0	4.0	10.0	10.0	10.0	10.0	5.0	7.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	30.0	30.0	30.0	6.0	1.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	17.0	7.0	8.0	0.0	0.0	0.0	10.0	10.0	10.0	6.0	9.0	5.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	30.0	29.0	29.0	5.0	0.0	0.0	10.0	10.0	10.0	9.0	4.0	5.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-Pf/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	30.0	29.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	30.0	30.0	28.0	0.0	1.0	0.0	10.0	10.0	10.0	7.0	2.0	1.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	30.0	28.0	14.0	15.0	0.0	0.0	10.0	10.0	6.0	10.0	9.0	0.0

RESULTS

Table 5 *(continued)*

Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)		
			200 parasites/µl			200 parasites/µl			2000 parasites/µl			2000 parasites/µl		
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C
			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined		
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	30.0	30.0	30.0	26.0	4.0	25.0	10.0	10.0	10.0	10.0	10.0	10.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	29.0	29.0	30.0	5.0	3.0	0.0	9.0	10.0	10.0	9.0	10.0	10.0
Pf and Pv														
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	12.0	10.0	12.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	30.0	30.0	30.0	NA	NA	NA	9.0	10.0	10.0	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	12.0	2.0	0.0	NA	NA	NA	10.0	10.0	9.0	NA	NA	NA
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	30.0	30.0	27.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[a]	05FK100	Standard Diagnostics Inc.	30.0	30.0	29.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b]	05FK100	Standard Diagnostics Inc.	8.0	1.0	1.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	30.0	30.0	11.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Pan only														
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0

NA, not applicable

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

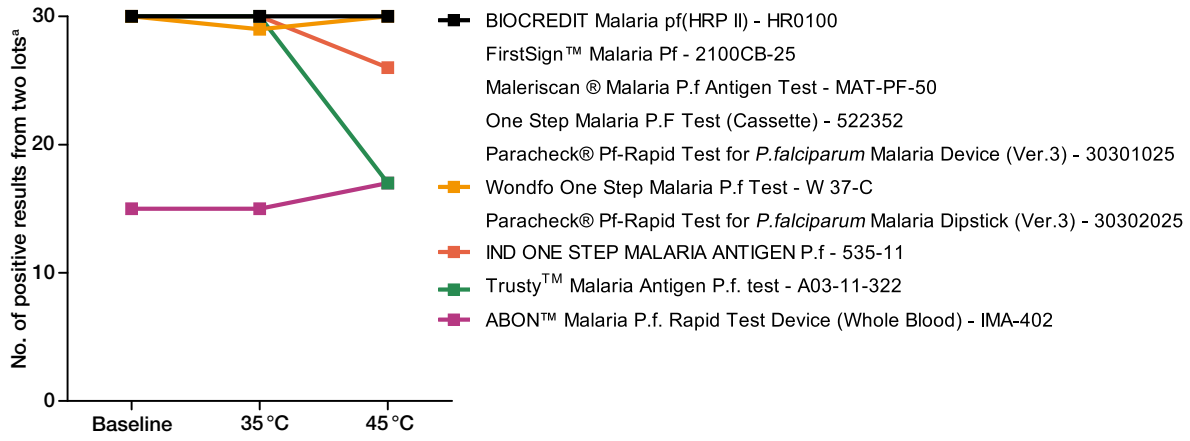
[a] Results presented in the table are based on stability of a pf-HRP2 line

[b] Results presented in the table are based on stability of a pf-pLDH line

[c] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

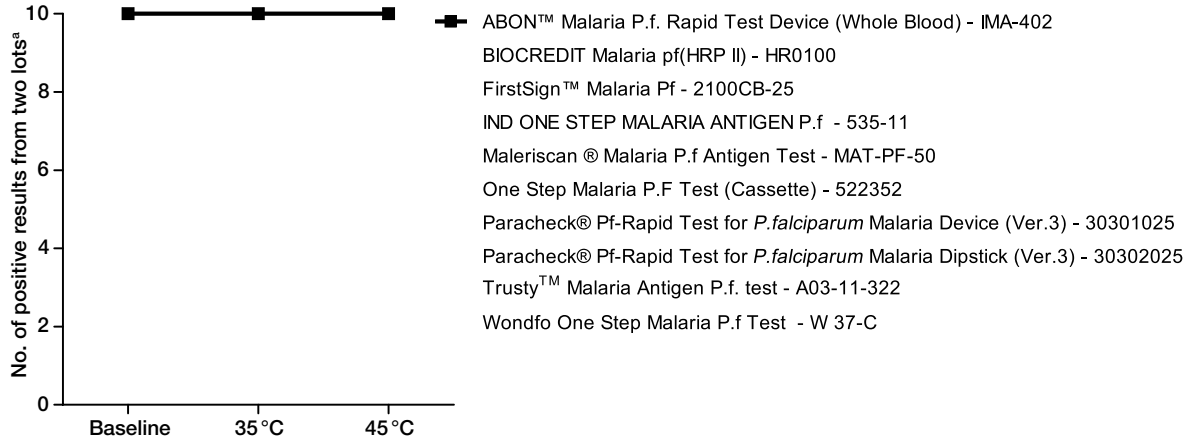
12.1. *P. falciparum* test lines

Figure 16: Heat stability of *P. falciparum* specific test line of *P. falciparum* only tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



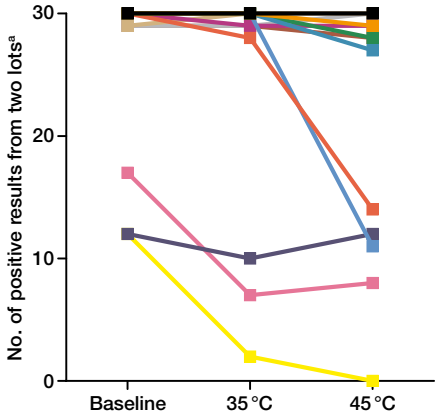
[a] Maximum score is 30 (15 tests x 2 lots)

Figure 17: Heat stability of *P. falciparum* specific test line of *P. falciparum* tests against a high density *P. falciparum* sample (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



[a] Maximum score is 10 (5 tests x 2 lots);

Figure 18: Heat stability of *P. falciparum* specific test line in combination tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.

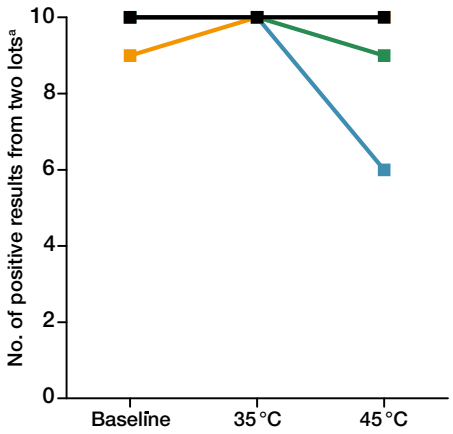


- ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
- CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
- CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
- Core Malaria Pan Pf - MAL-190024
- EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
- FalciVax™ - Rapid test for Malaria Pv/Pf - 50300025
- HiSens Malaria Ag P.f/P.v Combo Card - HR3123
- HiSens Malaria Ag P.f/VOM Combo Card - HR3323
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- Humasis Malaria P.f/P.v Antigen Test - AMFV-7025
- IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST - 535-10
- Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
- Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
- Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO - M161
- Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO - M171
- NanoSign Malaria pf/pan Ag 3.0 - RMAP10
- ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
- ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
- ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
- Parascreen® - Rapid test for Malaria Pan/Pf - 50310025
- RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST - MAL-PFV-CAS/25(100)
- SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b] - 05FK100
- OnSite Pf/Pan Ag Rapid Test - R0113C
- OnSite Pf/Pv Ag Rapid Test - R0112C
- Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
- MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
- FirstSign™ ParaView (Pan+Pf) - 2101CB-25
- AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b] - MFV-124F
- SD BIOLINE Malaria Ag Pf/ Pan - 05FK66
- ICT MALARIA COMBO - ML02
- ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
- Trusty™ Malaria Antigen P.f./p.v. test - A03-12-322
- Malaria Pf/ PAN - GM004
- Malaria Pf/Pv - GM002
- One Step Malaria P.F/P.V Test (Cassette) - 523352

[a] Maximum score is 30 (15 tests x 2 lots)

[b] Refer to Table A4.11 for individual HRP2 and pf-pLDH test line performance

Figure 19: Heat stability of *P. falciparum* specific test line in combination tests against a high density *P. falciparum* sample (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation.

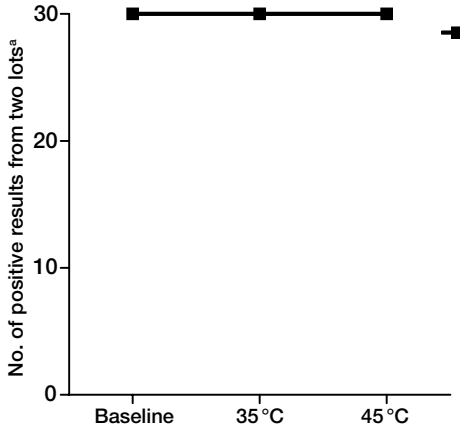


- ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
- AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b] - MFV-124F
- CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
- CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
- Core Malaria Pan Pf - MAL-190024
- EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
- FalciVax™ - Rapid test for Malaria Pv/Pf - 50300025
- FirstSign™ ParaView (Pan+Pf) - 2101CB-25
- HiSens Malaria Ag P.f/P.v Combo Card - HR3123
- HiSens Malaria Ag P.f/VOM Combo Card - HR3323
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- Humasis Malaria P.f/P.v Antigen Test - AMFV-7025
- ICT MALARIA COMBO - ML02
- IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST - 535-10
- Malaria Pf/ PAN - GM004
- Malaria Pf/Pv - GM002
- Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
- Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
- MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
- Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO - M161
- Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO - M171
- NanoSign Malaria pf/pan Ag 3.0 - RMAP10
- OnSite Pf/Pan Ag Rapid Test - R0113C
- OnSite Pf/Pv Ag Rapid Test - R0112C
- ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
- ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
- ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
- Parascreen® - Rapid test for Malaria Pan/Pf - 50310025
- RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST - MAL-PFV-CAS/25(100)
- SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b] - 05FK100
- Trusty™ Malaria Antigen P.f./p.v. test - A03-12-322
- Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
- SD BIOLINE Malaria Ag Pf/ Pan - 05FK66
- One Step Malaria P.F/P.V Test (Cassette) - 523352
- ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10

[a] Maximum score is 10 (5 tests x 2 lots)
[b] Refer to Table A4.12 for individual HRP2 and pf-pLDH test line performance

12.2. Pan-specific test lines

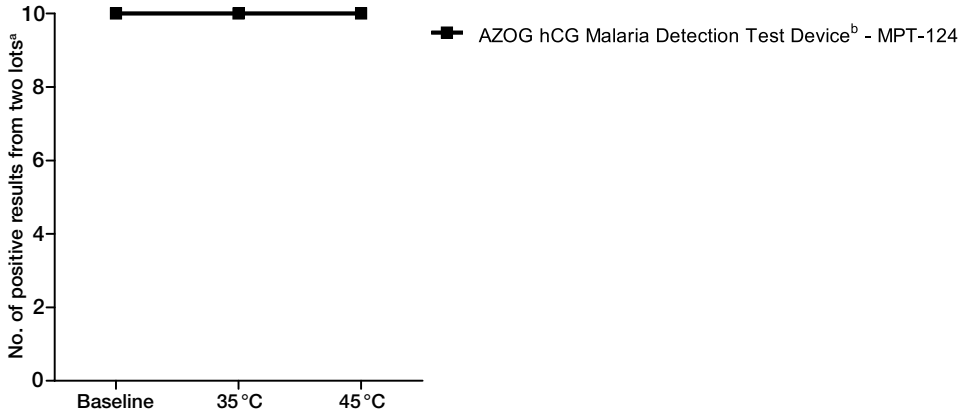
Figure 20: Heat stability of pan-line of pan-specific tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



- AZOG hCG Malaria Detection Test Device[b] - MPT-124

[a] Maximum score is 30 (15 tests x 2 lots)
[b] Single test line includes pf-pLDH, pan-pLDH and HRP2 antibodies

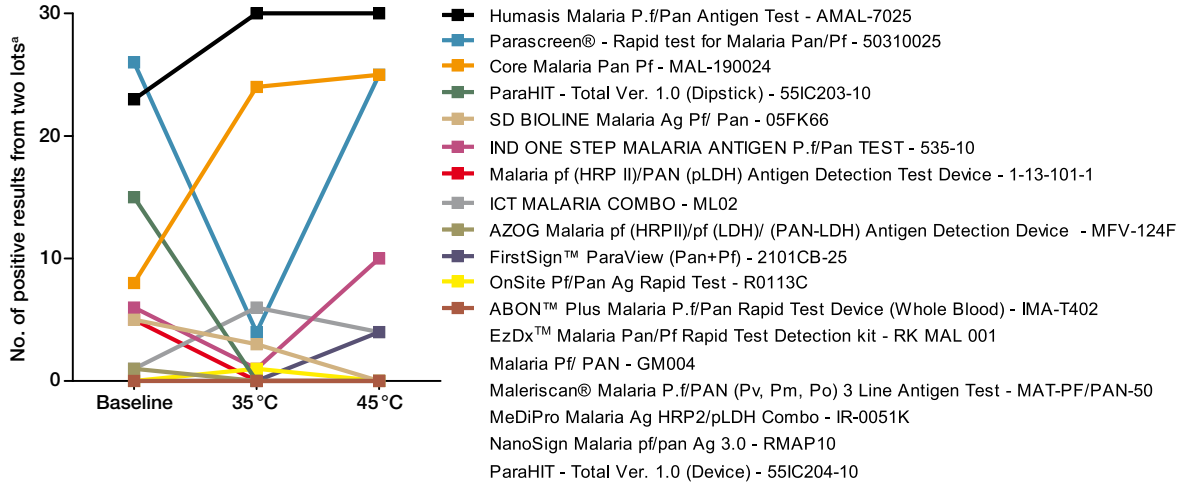
Figure 21: Heat stability of pan-line of pan-specific tests against a high density *P. falciparum* sample (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



[a] Maximum score is 10 (5 tests x 2 lots)

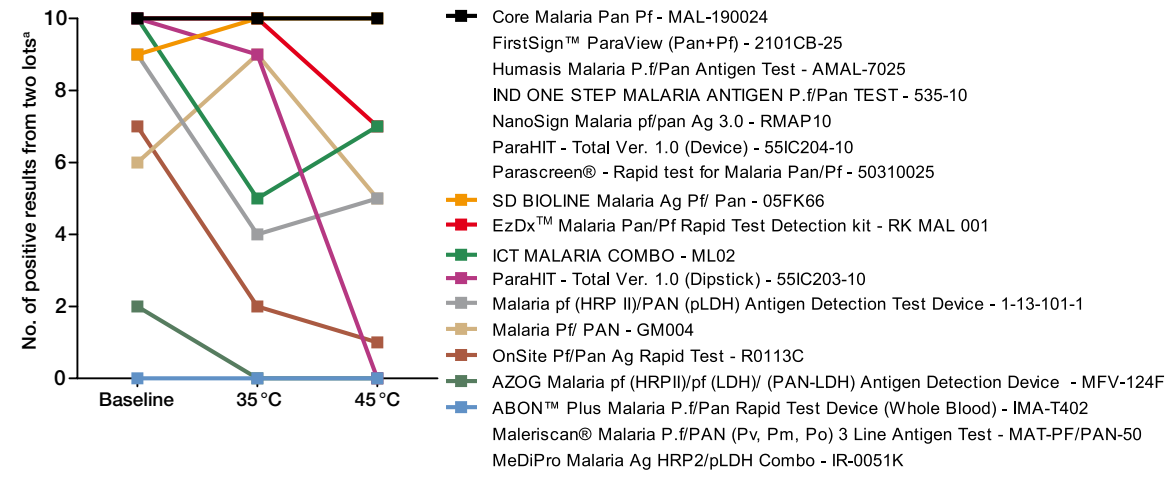
[b] Single test line includes pf-pLDH, pan-pLDH and HRP2 antibodies

Figure 22: Heat stability of pan-line of combination tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



[a] Maximum score is 30 (15 tests x 2 lots)

Figure 23: Heat stability of pan-line of combination tests against a high density *P. falciparum* sample (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



[a] Maximum score is 10 (5 tests x 2 lots)

13. EASE-OF-USE DESCRIPTION

After becoming proficient at using a product, two technicians jointly produced an agreed assessment of product usability. The results, which constitute a description of the product with emphasis on aspects considered of importance to ease-of-use in a field setting, are presented in Table 6. Importantly, the assessment does not compare blood transfer devices which are critical to both safety and accuracy of the testing procedure, and pose a significant challenge to many users. These can be varied by manufacturers with many products. Procurement decisions should consider which transfer devices are best suited to the intended users and discuss this with the manufacture prior to procurement. Ultimately, it is strongly recommended that RDT packaging, contents, safety and ease-of-use be assessed in the field as part of the product selection process (Table A5.1). Furthermore, end-users should be aware of major RDT anomalies that may be encountered in some production lots (Figure A5.2).

Table 6: Ease-of-use description of 48 malaria RDTs included in Round 4: WHO Malaria RDT Product Testing

Product	Catalogue number	Manufacturer	Blood safety[a]				Instruction quality[b]				Com-bined score (max.5)	Number of timed steps	Total time to result	Blood transfer device	Format	Language of instruction	Items included in package[c]
			Mixing wells involved	Retract-able needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result	Diagram of result & method	Score (max. 2)							
Pf only																	
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0	NA	1	1			x	2	3	1	15	pipette	Cassette	English	Cassette, Pipette, Buffer, Desiccant (no colour indicator)
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	1	NA	1	2			x	2	4	1	30	capillary tube	Cassette	English	Cassette, Capillary Tubes, Buffer, Desiccant (no colour indicator)
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	1	0	1	2		x		1	3	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swabs, Buffer, Desiccant (no colour indicator)
ICT MALARIA P.F.	ML04	ICT INTERNATIONAL	1	0	1	2			x	2	4	1	15	pipette	Cassette	English	Cassette, Pipette, Lancet, Alcohol Swabs, Buffer, Desiccant (Color-Change)
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	1	NA	1	2			x	2	4	1	25	na	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Desiccant (no colour indicator)
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1	NA	1	2			x	2	4	1	15	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	1	0	1	2			x	2	4	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (no colour indicator)
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	1	0	0	1		x		1	2	1	20	loop	Dipstick	English	Dipstick, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (no colour indicator)
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	1	1	1	3			x	2	5	1	15	loop	Cassette	English	Cassette, Transfer Loop, Lancet (retractable Needle), Alcohol Swab, Buffer, Desiccant (no colour indicator)
Pf and Pan																	
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	1	NA	1	2			x	2	4	2	15	pipette	Cassette	English	Cassette, Pipette, Buffer Desiccant (no colour indicator)
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	1	0	1	2		x		1	3	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swabs, Desiccant (no colour indicator)
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Desiccant (no colour indicator)
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	1	0	1	2		x		1	3	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swabs, Buffer, Desiccant (no colour indicator)
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	1	NA	1	2			x	2	4	1	30	loop	Cassette	English, French, Spanish	Cassette, Transfer Loop, Buffer, Desiccant (no colour indicator)
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	1	0	1	2			x	2	3	1	15	pipette	Cassette	English	Cassette, Pipette, Buffer, Lancet, Alcohol Swab, Desiccant (Color Change)
IND ONE STEP MALARIA ANTIGEN P.f/ Pan TEST	535-10	IND Diagnostics Inc.	1	NA	1	2			x	2	4	1	25	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Lancets, Desiccant (no colour indicator)
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (non- color-change)
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Desiccant (no colour indicator)

Table 6 *(continued)*

Product	Catalogue number	Manufacturer	Blood safety[a]				Instruction quality[b]				Com-bined score (max.5)	Number of timed steps	Total time to result	Blood transfer device	Format	Language of instruction	Items included in package[c]
			Mixing wells involved	Retract-able needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result	Diagram of result & method	Score (max.2)							
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0	NA	1	1			x	2	3	1	15	pipette	Cassette	English	Cassette, Pipette, Buffer, Desiccant (no colour indicator)
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	1	0	1	2			x	2	4	1	15	Loop	Cassette	English	Cassette, Transfer Loop, Buffer, Lancet, Desiccant (no colour indicator)
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	1	NA	1	2			x	2	4	1	30	pipette	Cassette	English	Cassette, Pipette , Buffer, Desiccant (no colour indicator)
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	1	0	0	1			x	2	3	1	25	capillary tube	Dipstick	English	Dipstick, Capillary Tubes, Alcohol Swabs, Lancets, Buffer, Test Tubes, Desiccant (Color Change)
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	1	0	1	2			x	2	4	1	25	capillary tube	Cassette	English	Cassette, Capillary Tubes, Alcohol Swabs, Lancets, Buffer, Desiccant (Color Change)
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	1	0	1	2		x		1	3	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swabs, Buffer, Desiccant (Color-Change)
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	1	NA	1	2		x		1	3	1	15	NA	Cassette	English, French, Spanish, Portuguese	Cassette, Buffer, Desiccant(no colour indicator)
Pf and Pv																	
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	1	0	1	2		x		1	3	1	20	loop	Cassette	English	Cassette, Transfer Loop, Lancet, Alcohol Swabs, Buffer, Desiccant (Color-Change)
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Buffer, Pipette, Desiccant (no colour indicator)
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Buffer, Pipette, Desiccant (no colour indicator)
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	1	NA	1	2			x	2	4	1	30	loop	Cassette	English, French, Spanish	Cassette, Transfer Loop, Buffer, Desiccant (no colour indicator)
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	1	NA	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Lancets, Desiccant (no colour indicator)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1	NA	1	2			x	2	4	1	15	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	1	NA	1	2			x	2	4	1	30	pipette	Cassette	English	Cassette, Pipette , Buffer, Desiccant (no colour indicator)
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	1	0	1	2			x	2	4	1	20	pipette	Cassette	English	Cassette, Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (no colour indicator)

Table 6: Ease-of-use description of 48 malaria RDTs included in Round 4: WHO Malaria RDT Product Testing *(continued)*

Product	Catalogue number	Manufacturer	Blood safety[a]				Instruction quality[b]				Com-bined score (max.5)	Number of timed steps	Total time to result	Blood transfer device	Format	Language of instruction	Items included in package[c]
			Mixing wells involved	Retract-able needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result	Diagram of result & method	Score (max. 2)							
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	1	0	1	2			x	2	4	1	20	loop	Cassette	English	Cassette, Transfer Loop, Buffer, Alcohol Swabs, Desiccant (no colour indicator)
RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/PV TEST	MAL-PFV-0207	Hema Diagnostic Systems, LLC	1	NA	1	1			x	2	3	1	15	NA	Modified dipstick	English	Device, Buffer, Desiccant (no colour indicator), Cover
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	1	NA	1	2		x		1	3	1	15	NA	Cassette	English	Cassette, Buffer, Desiccant(no colour indicator)
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)
Pan only																	
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	1	NA	1	2			x	2	4	1	20	NA	Cassette	English	Cassette, Buffer, Desiccant (no colour indicator)

NA, not applicable

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

[a] Mixing wells involved: Yes=0; No=1; Retractable needle: Yes=1; No=0; Strip exposed (not within card or cassette): Exposed=0, Covered=1

[b] No diagrams=0; Diagram of the results=1; Diagram of result and method=2

[c] These are not necessarily standard kit contents. Procurers should verify with the manufacturers what materials accompany test kits and ensure they procure all the required accessories at the same time.

[d] Instructions pamphlet not included in the original packaging

14. DISCUSSION OF KEY FINDINGS

This report describes the performance of many of the available malaria antigen-detecting RDTs manufactured under the ISO 13485:2003 quality standard. Malaria RDTs have the potential to provide a huge step forward in the management of febrile illness in malaria-endemic areas. To be useful in this context, malaria RDTs must have adequate:

i. sensitivity, to detect nearly all clinically-significant cases of malaria;

ii. specificity, to accurately discriminate non-malarial febrile illness from malaria, to ensure appropriate management and accurate disease monitoring;

iii. stability, for accuracy to be maintained after transport and storage in ambient conditions;

iv. ease-of-use and safety, to allow safe and correct preparation, and accurate interpretation of results.

In order to assist National Malaria Control Programmes and other procurement agencies in the selection of products appropriate to their needs, malaria RDTs were evaluated in terms of these four major requirements. The panel used successfully discriminated between the RDTs evaluated, showing a considerable range of performance. Importantly, a number of products demonstrated a high rate of antigen detection combined with a low false-positive rate and good heat (thermal) stability, attributes essential if they are to be relied on as a basis for malaria treatment decisions in most endemic populations. Deserving special note in Round 4, is the marked improvement in PDS of many products re-submitted for evaluation from previous rounds (Table S1, S3). Against the 200 parasites/µl panels, the mean and median PDS of the 13 re-submitted products rose from 84.0% to 87.7% and 85.0% to 89.8%, respectively for *P. falciparum* detection. For the nine products which detected *P. vivax*, the mean and median rose from 59.1% to 72.6% and from 80.0% to 88.2%, respectively.

The results for re-submitted products in Round 4 replace those of previous rounds. The programme adheres to a working definition of 'product' which lays out specific conditions/modifications that denote a change in product.

Overall the Round 4 mean PDS for low densities *P. falciparum* and *P.vivax* samples was 81.6% and 51.3%, respectively. This represents an increase for *P. falciparum* compared with previous Rounds 1, 2 and 3 (67.2%, 69.9%, 75.5%, respectively). For *P. vivax* the mean PDS of 51.3% was comparable to previous rounds, i.e. 36.0%, 58.9% and 47.1% in Rounds 1, 2 and 3, respectively. In addition, the mean false-positive rate was 4.5% and is lower than 5.9% in Rounds 3; furthermore, the median FP rate fell from 1.8%, 2.9%, 1.0% (Rounds 1, 2 and 3) to 0.6 % in Round 4. Overall, the trend is towards better performing RDTs associated with the period of the WHO-FIND RDT Evaluation Programme.

The principal results in this report are presented in Tables 3 and 4. The tables group the RDTs by type, depending on what they are supposed to detect, e.g. *P. falciparum* only, *P. falciparum* and non-*falciparum* species, as well as *P. falciparum* and *P.vivax* or Pvom-specific and pan- *only,* or all malaria species without discrimination. Note that the evaluation only tests against *P. falciparum* and *P. vivax* samples, and does not therefore indicate whether a product intended to detect other species can do so. Panel detection scores at both high and low parasite concentrations are presented, as are false-positive rates, and the percentage of invalid test results. Tests in each category are listed alphabetically, but the results are colour-coded to assist the reader in quick interpretation of the data. These colour codes are intended to be used to quickly compare performance in the different categories and not as performance cut-offs to guide test selection or procurement. WHO recommendations for procurement should be referred to regarding these criteria[1]. When choosing an appropriate product, it is important to also review the stability results (Table 5) in the context of the expected conditions of transport and storage of the RDTs in the field.

This evaluation is performed against a standardized panel of cultured *P. falciparum* and frozen blood samples by experienced technicians in a research laboratory, and is not therefore a field evaluation of RDT accuracy in a specific epidemiological context in the hands of intended users. The panel is designed to mimic fresh blood samples from actual cases as closely as possible, while allowing direct comparison of a large number of products simultaneously in a manner that controls for confounding factors and is calibrated to a level likely to discriminate performance differences of various products. In interpreting the results, it is therefore important that the following discussion points are taken into account.

14.1. Panel Detection Score (PDS) and its relationship to sensitivity

Evaluation of the RDTs against the Phase 2 wild-type parasite panel with parasite densities of 200 parasites/µl (Figures 8, 9) revealed a wide range of frequency and consistency of antigen detection between products, recorded as the "Panel Detection Score" (PDS). As expected, testing at higher parasite densities (2000 [or 5000] parasites/µl) results in smaller differences in performance. As two tests each from two different lots were tested at 200 parasites/µl, and as all four results had to be positive for a sample to be considered *detected* by an RDT, a positive result indicated both the ability of a product to detect the target antigen in the sample, and to do this consistently (both tests from both lots). Parasite densities of around 200 parasites/µl should be detected to ensure high field sensitivity for clinically-significant malaria infection in many malaria-endemic populations *(6).*

[1] Information note on interim selection criteria for procurement of malaria rapid diagnostic tests (RDTs) (April 2012) http://www.who.int/entity/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf (accessed 15 October, 2012)

The PDS against the panels used in this evaluation is expected to differ from the test sensitivity in a specific clinical setting for five main reasons.

i. Performance may vary between lots or batches of the same product. Variability in lot performance is an issue with all diagnostics, and it cannot be guaranteed that the results found here will predict results from subsequent RDT lots. It is important to test lots prior to distribution to the field, to ensure that expected performance is maintained (see Section 15.2).

ii. In clinical settings, patients show a wide variety of parasite densities, the range of which will depend on the local epidemiology of the disease. The magnitude of the parasite density in the population tested affects the clinical sensitivity of the test. PDS against the test panel of blood samples diluted to 200 parasites/µl are likely to underestimate the clinical sensitivity of an RDT in areas of high-transmission where symptomatic patients often have much higher parasite densities in their blood. Many tests that showed only moderate detection of the 200 parasites/µl panel may perform well in such settings, as indicated by the better PDS of most products against the panel set at 2000 parasites/µl.
Importantly, when interpreting Figures S1, S2, 7-9, and the colour coding in Tables 3, 4, **the small differences in panel detection scores found among the better-performing RDTs in this evaluation are unlikely to result in noticeable differences in clinical sensitivity, and other issues such as stability, cost, prior experience and training of the intended users, ease of use (Annex 5b) and manufacturing capacity may be equally important factors in test selection.** Taking into consideration the parasite density of the target populations and the likely field sensitivity of RDTs, it is important to note that, even in areas with high transmission and strong malaria immunity, populations may include individuals with low parasite densities but clinically significant infections (e.g. young children, pregnant women, those regularly using bed nets, immigrants, and others with reduced immunity). The ability to detect low parasite density infections reliably, therefore, remains important in these cases. As some countries move towards elimination, population immunity will decrease and it will become increasingly important to use diagnostic tests that detect low parasite densities (i.e. with high PDS against 200 parasites/µl samples).

iii. Performance of tests against the challenge panel may sometimes not be predictive of sensitivity in clinical testing where antigen expression by certain parasite populations differs greatly from that in the panel. Specifically, there is evidence that *P. falciparum* strains in some areas of South America do not express HRP2 antigens due to gene deletions *(19, 21)*. If a significant proportion of parasites in a given area do not express HRP2, it is necessary to use tests detecting other target antigens (eg. pLDH or aldolase in the case of HRP2,3 deletions). The distribution of such strains is currently being mapped. To date, no parasite populations with high frequencies of non-expression of target antigens have been demonstrated outside of South America.

iv. The conditions under which RDTs are transported and stored can alter their field sensitivity. The tests used in this evaluation were shipped and stored under conditions intended to safeguard against degradation caused by high temperature or other extreme conditions. If similar precautions are not taken with purchased RDTs, loss of performance could result. Ambient temperatures of storage conditions vary widely in settings where these tests are commonly used, as do temperatures during transport, and requirements for heat stability of a product will therefore differ. Tests should be transported and stored well within the temperature range recommended by the manufacturer, and extremes of temperature avoided (*23, 24*).

v. Diagnostic sensitivity and specificity are dependent on the quality of preparation and interpretation of the tests. Highly trained individuals performed all the testing in this product evaluation. In clinical settings, malaria RDTs will often be used by health workers with limited training and supervision. Simplicity of design and clearly-interpretable results will have an influence on ensuring that the technical proficiency of a product translates into accurate diagnosis in the field[1].

14.2. False-positive rate and specificity

False-positive rates are reported here against a panel of clean-negative samples taken from blood donated in low-transmission settings by people without malaria symptoms. In addition, false-positive rates were calculated against a smaller number of samples with specific characteristics that affect the likelihood of a false-positive result from an immuno-diagnostic test (e.g. rheumatoid factor, anti-nuclear antibody), or that may be of significance in a specific population in malaria-endemic areas (e.g. leishmaniasis, dengue). The importance of these results will vary with the intended area of use. High false-positive rates against samples of blood from dengue patients, for example, may not be a significant factor to consider in regions where dengue does not occur. In view of the small number of samples in each category in this evaluation, the **results should be considered primarily as a guide to highlight potential cross-reactions that will require close monitoring if relevant to the target population.**

In general, it is preferable to procure a product with a low rate of false-positive reactions. In the case of many diagnostic tests, a trade-off must be made between a preference for a high rate of antigen detection (sensitivity) and a low false-positive rate (specificity). The context in which the test will be used will guide the relative importance of these two factors in choosing one product over another. Overall, in this evaluation there was no correlation of lower PDS (loss of sensitivity) associated with low false-positive rates (high specificity). A number of products attained both a high PDS and a low false-positive rate.

[1] Examples available here: *http://www.wpro.who.int/sites/rdt/using_rdts/training/main.htm* (accessed 15 October , 2012); *http://www.finddiagnostics.org/programs/malaria/find_activities/rdt-job-aids/* (accessed 15 October, 2012)

14.3. Heat (thermal) stability

RDTs in this evaluation were held for two months at 35°C and 45°C and 75% humidity and then retested to evaluate stability at these temperatures. The importance of thermal stability will vary according to the ambient conditions under which a product is expected to be transported and stored. Thus, stability at high temperatures will be vital if an RDT is to be stored at clinic level in a country where ambient temperatures can reach 45°C in the hot season, but less critical in a high-altitude or cooler environment where temperatures rarely rise above 35°C. Many commercially-available RDTs list 30°C as the maximal storage temperature. Higher temperatures were used for this evaluation because it is common for malaria-endemic countries to have maximum ambient temperatures of 35°C or above, although the use of cool storage methods can allow storage and use of products designed for storage below these temperatures. Where transport and storage of RDTs is likely to occur at high ambient temperatures, heat (thermal) stability should be seen as a significant factor in ensuring maintenance of sensitivity.

High humidity will accelerate the degradation of malaria RDTs and other lateral flow tests. All the products in this evaluation were packaged in individual envelopes that contain a desiccant and are designed to be moisture-proof. This allows the user to open the envelope of a specific test at the time of use, limiting exposure to high humidity. During the stability testing phase of this evaluation, RDTs were stored at 75% humidity. The packaging should, if in good condition, protect the contents from exposure to high humidity during storage. As such, the stability testing results presented here provide an assessment of both the stability of the RDT and the quality of its packaging.

Currently, we are only able to assess the stability of test lines to detect cultured *P. falciparum* samples. Several products showed high stability at the temperatures and time periods used in this evaluation. In general, in this round as in previous ones pan-specific lines (pLDH) performed less well at baseline and were less stable than HRP2 test lines, rendering post incubation stability assessment difficult to interpret.

Though temperature and humidity were held constant in this evaluation, temperatures in the field fluctuate with time of day and season. While two months' storage at a set temperature cannot accurately predict long-term stability under field conditions, loss of parasite detection over this period indicates a likelihood that significant sensitivity will be lost when similar or higher storage temperatures comprise a significant amount of the storage time, and indicates likelihood of a higher susceptibility to degradation during short periods of exposure to much higher temperatures, such as during transport *(25, 26).*

14.4. Ease-of-use description

The sensitivity and specificity of RDT results are dependent on the quality of preparation and interpretation of the test. In general, a simpler format with fewer steps or fewer required extraneous materials is likely to be prepared and interpreted more reliably. Thus, cassette-format RDTs are generally more reliably prepared and interpreted than products in dip-stick format *(27).* The extra cost involved in such a format may be offset by the advantages of increased accuracy and, in some cases, less additional equipment required to perform them.

The method of blood transfer from the patient to the test is important for the safety of the user, and for the accuracy of volume of blood transferred. Devices for blood transfer are supplied with RDTs, and vary widely in design, and accuracy (*20*). The performance of blood transfer devices was not formally assessed in this evaluation, as blood was transferred from a tube by a micro-pipette to ensure the manufacturer-specified volume was used. **Programmes procuring RDTs should consider the adequacy of the blood transfer device supplied, including previous experience of health workers and the costs and time required for re-training.** It may often be appropriate to discuss with manufacturers the possibility of changing the blood transfer device from that normally supplied.

Clarity of results is important to test interpretation. A clearly visible (intense) test line is less likely to be overlooked than a line that is barely visible. While reading proficiency and adequate work places should always be ensured, health workers may sometimes have sub-optimal vision or work in conditions of inadequate lighting. The intensity of the line of the test band is closely associated with the PDS achieved by RDTs in this report (Tables A4.2, A4.3).

The importance of format and simplicity of test design will depend on the intended end-users. Trained laboratory technicians may handle a complicated procedure more reliably than village-level volunteers with limited supervision. In all cases, specific proficiency-based training and adequate supervision should be included in any RDT-based diagnostic programme, and clear instructions should be provided in a language and format appropriate for the end-user *(27–29)*. **Annex 5b provides guidance on conducting a field-based ease-of-use assessment (Table A5.1) and illustrates examples of RDT anomalies (Figure A5.2).**

14.5. Inter-lot variability

This testing programme evaluated only two production lots of each product. Malaria RDTs are complex biological products made of components commonly supplied from multiple sources, and subject to various conditions during manufacture that may affect the quality of the final product. All manufacturers entered in this evaluation provided at least one current ISO 13485:2003 certification for a manufacturing facility. This standard is designed to give assurance of consistency of quality of the final product, if correctly implemented. The results presented here indicate that inter-lot variability does occur, and WHO strongly recommends that a sample of RDTs from each production lot be tested prior to dissemination to the field to ensure it meets an appropriate standard. This can be facilitated by WHO through two WHO-recognized lot testing facilities (Section 15.2).

Since inter-test variability also occurs, this will be detected to some extent by routine lot testing. Ensuring manufacturers have good manufacturing standards should minimize the likelihood of inconsistencies due to poor practice in the manufacturing process. Culture-based panels[1] that are subsets of the Phase 1 panel of this evaluation are available as reference standards for manufacturers to set their own lot-release criteria against.

14.6. Target antigens and species

Malaria RDTs included in this evaluation detect one or more of three parasite antigens (HRP2, pLDH, and aldolase) in various combinations. HRP2 is present only in *P. falciparum*, whereas aldolase and pLDH are present in all four species and may be used as pan or all-species targets. Some tests use differences in pLDH sequences between species as a means to differentiate *P. falciparum* from *P. vivax* and other species. There is considerable overlap in the PDS of products targeting the different antigens in this evaluation. While the products with the highest PDS for *P. falciparum* targeted HRP2, a number of pLDH-detecting products demonstrated high PDS against *P. vivax*. The thermal stability of tests targeting these different antigens also overlapped for high parasite density samples.

The choice of RDT should take target antigen into account: HRP2-detecting RDTs should not be used in areas where high rates of HRP2 non-expression occur (*19,21*). Tests detecting only HRP2 (without pLDH or aldolase lines) will have limited utility where non-*falciparum* malaria is common. pLDH (and possibly aldolase) RDTs may have further advantages where antigen persistence (common with HRP2) may result in a high false-positive rate in areas where early retesting in the weeks immediately after treatment is common.

The required sensitivity of a test may also vary with species; a less sensitive test may be acceptable for detection of *P. vivax* compared to detection of *P. falciparum*, as severe outcomes due to missed diagnoses are less likely. Use of a sufficiently sensitive pan-specific-only test may be appropriate in areas where both *P. falciparum* and *P. vivax* occur, if all infections were to be managed initially as a *P. falciparum* infection with artemisinin-based combination therapy (ACT), but species-specific monitoring data would be lost. Tests with high PDS for both *P. falciparum* and *P. vivax* were demonstrated in this and previous rounds of product testing *(3, 4, 5)*.

It should be noted that pan-species tests were not evaluated for detection of *P. ovale* or *P. malariae* in this evaluation due to lack of sources of suitable mono-species infections of these parasites.

[1] To access these panels, contact *Malaria_rdt@who.int*, *cunninghamj@who.int* or *info@finddiagnostics.org*.

15. USING THESE RESULTS TO ENSURE QUALITY OF DIAGNOSIS IN THE FIELD

This report provides data to guide malaria control and management programmes in selecting products likely to perform to a high standard in the particular contexts in which the programme operates. The final decision on product selection requires that this data be considered in a systematic way, taking into context the distribution of parasite densities of the target population among whom the tests will be used, and the experience and training of the intended users. Further information should be sought from the manufacturer and other sources. An algorithm to guide this process is given in Annex 5a[1] and detailed guidance is provided by WHO elsewhere (*7*).

While malaria RDTs can be applied in a number of settings, the greatest potential for impact on public health is in extension of access to accurate, parasite-based diagnosis of malaria to regions and populations where good quality microscopy-based analysis is impractical to maintain. This makes possible the implementation of recent WHO recommendations on universal parasite-based diagnosis prior to anti-malarial therapy *(2)*. This currently applies to most people at risk of malaria in endemic countries (*1*). In many settings where RDTs have been introduced, the true rate of parasitaemia has been found to be considerably lower than expected, allowing health systems to reduce wastage of anti-malarial medicines and to focus on the appropriate management of non-malarial causes of fever, including early pneumonia and sepsis. A successful RDT programme must therefore address not just malaria but also the management of other common and severe febrile illnesses that occur locally, in the differential diagnoses of malaria, if the potential full public health impact of an RDT programme is to be achieved.

15.1. Beyond procurement

Diagnostic tests normally represent the starting point in a health system intervention, and their use presumes that appropriate patient management, based on testing, will follow. Thus, successful introduction of RDTs requires careful planning beyond rational procurement to ensure consistent supplies of all necessary materials (including gloves, sharps disposal containers, and supplies required for further case management), training of end-users, community sensitization, and monitoring of diagnostic quality and results. This extends beyond malaria management to management of other febrile diseases and health service delivery systems, and requires an integrated approach with other health programmes impacting on the management of febrile illness.

This report provides information to guide procurement of RDTs within this framework. A number of factors beyond performance characteristics reported here must influence procurement decisions. An example algorithm, including ease-of-use assessment, is provided to guide these decisions in Annexes 5a and 5b.

Details of implementation will vary widely between programmes according to local capacity and needs. Further recommendations on budgeting, planning and implementation can be found in Annex 6 and in the relevant WHO guidance document (*30*).

15.2. Lot testing

Complementary to the product testing programme, WHO and FIND currently support laboratories that perform continual quality assurance of RDTs in the form of lot testing. This programme responds to requests from national malaria programmes, manufacturers, and procurement bodies to assess the quality of RDT lots prior to purchase or when they arrive in country, prior to dispersal to the field and for clinical use. Testing is performed against parasite-positive and negative panels prepared and characterized in the same way as the panels used in this evaluation. A number of other national institutions have also developed this capacity. Lot-testing reassures countries that the product they have purchased is performing to a high standard before distribution, and helps to ensure that manufacturers produce consistently good lots and improve their products.

Countries and/or manufacturers ship between 125–175 RDTs to the regional WHO-recognized lot testing centres where they are evaluated against a small panel of parasites at high and low parasite densities and negative samples (Figure 2 - IPC, RITM). They are subsequently incubated at a temperature close to the manufacturer's specified storage temperature and retested after 18 months. Initial results are available after five days and then sent again after subsequent retesting. Details of the protocol can be found in the published methods manual for lot testing *(18)*. National malaria programmes and procuring agencies are encouraged to participate in the lot testing programme.

To access lot testing through the WHO-FIND programme, contact: *Malaria_rdt@who.int* or *info@finddiagnostics.org* at least 2 weeks before RDTs are ready for shipment. Further information is available at *www.wpro.who.int/sites/rdt/who_rdt_evaluation/lot_testing.htm*, or through *www.finddiagnostics.org*

[1] An interactive guide designed to help short-list test according to individual programme needs, based on the performance of tests in rounds 1-4of the WHO Product Testing Programme can be found at *http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp*

16. CONCLUSIONS

This report adds to the large data set on malaria RDT performance published annually since 2009 after the first, second and third rounds of evaluations *(3, 4, 5)*. The product testing programme continues to be a landmark in the field of malaria RDT evaluations in terms of the number of products evaluated and its comprehensiveness. New laboratory methods have been developed and validated to support parasite characterization and this work generated new findings regarding the variation in antigen content at similar parasite densities and the variation in the structure and expression of HRP proteins. The publication of the WHO Product Testing Rounds 1-3 results has impacted on the procurement practices of countries and procurement agencies, and contributed to the shift in the malaria RDT market towards better performing products (*1*). The Report of Round 4 further adds to the number of well-performing RDTs for which comprehensive performance data are now available, and provides updated data on 13 products that have been re-submitted following product modifications.

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ANNEXES

Annex 1: Characteristics of rapid malaria tests in Round 4

Manufacturer	Product name	Catalogue number	Plasmodium species targeted (F = *P. falciparum* V = *P. vivax* O = *P. ovale* M = *P. malariae* P = PAN; major Plasmodium species)	Target antigen[a](s)	Sequence and type of bound antibody[b]				Required volume (µl) of whole blood	Buffer drops (µl)	Minimum time to results[c] (mins)	Maximum reading time (mins)	Results Interpretation[d] (Type A–J)	Format type[e]
					C	T1	T2	T3						
ABON Biopharm (Hangzhou) Co. Ltd	ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	F	HRP2	√	HRP2		–	10	3(120)	15	20	A	A
	ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	F,P	HRP2, aldolase	√	aldolase	HRP2	–	10	3 drop - Well 2; after 5 mins 1drop -Well1	15	20	C	A
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2(60)	20	-	E	A
	CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	F,V, O,M	pvom-pLDH, HRP2	√	pvompLDH	HRP2	–	5	2(60)	20	-	H	A
Access Bio Ethiopia	ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2(60)	20	-	E	A
	ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	F,V, O,M	pvom-pLDH, HRP2	√	pvompLDH	HRP2	–	5	2(60)	20	-	H	A
Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	F,P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	4(110+/-5)	20	30	C	A
Artron Laboratories Inc.	Trusty™ Malaria Antigen P.f. test	A03-11-322	F	HRP2	√	HRP2		–	5	4	20	40	A	A
	Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	4	20	40	E	A
AZOG, INC.	AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	F,P	pan-pLDH, pf-pLDH, HRP2	√	panpLDH	pfpLDH	HRP2	5	2(80)	20	-	L	A
	AZOG hCG Malaria Detection Test Device	MPT-124	P	pan-pLDH, pf-pLDH, HRP2	√	hCG	HRP2, pf-pLDH, panpLDH	–	5	2(80)	20	-	B	A
Bhat Bio-Tech India (Pte.) Ltd.	Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	F	HRP2	√	HRP2		–	5	2	20	20	A	A
	Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	F,P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2	20	20	C	A
Bioland Ltd.	NanoSign Malaria pf/pan Ag	RMAP10	F,P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	4	15	30	C	A
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (Cassette)	522352	F	HRP2	√	HRP2		–	5	3(100)	15	20	A	A
	One Step Malaria P.F/P.V Test (Cassette)	523352	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	3	15	20	E	A
Core Diagnostics Ltd.	Core Malaria Pan Pf	MAL-190024	F,P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2	20	-	C	A
CTK Biotech, Inc.	OnSite Pf/Pv Ag Rapid Test	R0112C	F,V	HRP2, pv-pLDH	√	HRP2	pvpLDH	–	5	3(100-150)	30	-	F	A
	OnSite Pf/Pan Ag Rapid Test	R0113C	F,P	HRP2, pan-pLDH	√	HRP2	panpLDH	–	5	3(100-150)	30	-	D	A
Formosa Biomedical Technology Corp.	MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	F,P	HRP2, pan-pLDH	√	panpLDH	HRP2	–	10	3(90)	15	30	C	A
Genomix Molecular Diagnostics pvt. Ltd.	Malaria Pf/Pv	GM002	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2	20	-	E	A
	Malaria Pf/ PAN	GM004	F, P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2	20	-	C	A
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo One Step Malaria P.f Test	W 37-C	F	HRP2	√	HRP2		–	5	6(135-150)	15	30	A	A
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Combo Card	HR3123	F,V	pvpLDH, HRP2	√	pvpLDH	HRP2	–	5	2(60)	20	-	E	A
	HiSens Malaria Ag P.f/VOM Combo Card	HR3323	F,V, O,M	pvom-pLDH, HRP2	√	pvompLDH	HRP2	–	5	2(60)	20	-	H	A
Hema Diagnostic Systems, LLC	RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/ PV TEST	MAL-PFV-0207	F, V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	10	diluent pod; wait 7-10mins	15	30	E	E
	RAPID 1-2-3® HEMA CASSETTE MALARIA PF/ PV TEST	MAL-PFV-CAS/25(100)	F, V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2 Port B	20	-	E	A
Humasis, Co., Ltd.	Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	F, P	pan-pLDH,HRP2	√	panpLDH	HRP2	–	5	4(120)	30	30	C	A
	Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	4(120)	30	30	E	A

Annex 1 *(continued)*

Manufacturer	Product name	Catalogue number	Plasmodium species targeted (F = *P. falciparum* V = *P. vivax* O = *P. ovale* M = *P. malariae* P = PAN; major Plasmodium species)	Target antigen[a](s)	Sequence and type of bound antibody[b] C	T1	T2	T3	Required volume (µl) of whole blood	Buffer drops (µl)	Minimum time to results[c] (mins)	Maximum reading time (mins)	Results Interpretation[d] (Type A–J)	Format type[e]
ICT INTERNATIONAL	ICT MALARIA COMBO	ML02	F,P	aldolase, HRP2	√	HRP2	aldolase	–	5	5	15	-	D	A
	ICT MALARIA P.F.	ML04	F	pf-pLDH	√	pfpLDH		–	5	5	15	-	A	A
IND Diagnostics Inc.	IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	F,P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	4	25	30	C	A
	IND ONE STEP MALARIA ANTIGEN P.f	535-11	F	HRP2	√	HRP2		–	5	3	25	30	A	A
Medisensor, Inc.	Medisensor Malaria HRP2/pLDH (Pf/PV) COMBO	M161	F, V	HRP2, pv-pLDH	√	pvpLDH	HRP2	–	5	2(60)	20	-	E	A
	Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	F,V, O,M	HRP2, pvom-pLDH	√	pvompLDH	HRP2	–	5	2(60)	20	-	H	A
Orchid Biomedical Systems (Tulip Group)	Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver. 3)	30301025	F	HRP2	√	HRP2		–	5	2	20	-	A	A
	Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver. 3)	30302025	F	HRP2	√	HRP2		–	5	4(200)	20	-	A	D
RapiGen Inc.	BIOCREDIT Malaria pf(HRP II)	HR0100	F	HRP2	√	HRP2		–	5	3	30	30	A	A
SPAN DIAGNOSTICS LTD.	ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	F, P	aldolase, HRP2	√	aldolase	HRP2	–	8	4(200)	25	30	C	D
	ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	F, P	aldolase, HRP2	√	aldolase	HRP2	–	8	4(200)	25	30	C	A
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag Pf/ Pan	05FK66	F, P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	4	15	30	C	A
	SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	F, V	pf-pLDH, pv-pLDH, HRP2	√	pvpLDH	pfpLDH	HRP2	5	4	15	30	K	A
Unimed International Inc.	FirstSign™ Malaria Pf	2100CB-25	F	HRP2	√	HRP2		–	5	2	20	-	A	A
	FirstSign™ ParaView (Pan+Pf)	2101CB-25	F, P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2	20	-	C	A
United Biotech, Inc.	Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	F, P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2(80)	20	-	C	A
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2(80)	20	-	E	A
Zephyr Biomedicals	FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	F,V	pv-pLDH, HRP2	√	pvpLDH	HRP2	–	5	2	20	-	E	A
	Parascreen® - Rapid test for Malaria Pan/Pf	50310025	F, P	pan-pLDH, HRP2	√	panpLDH	HRP2	–	5	2	20	-	C	A

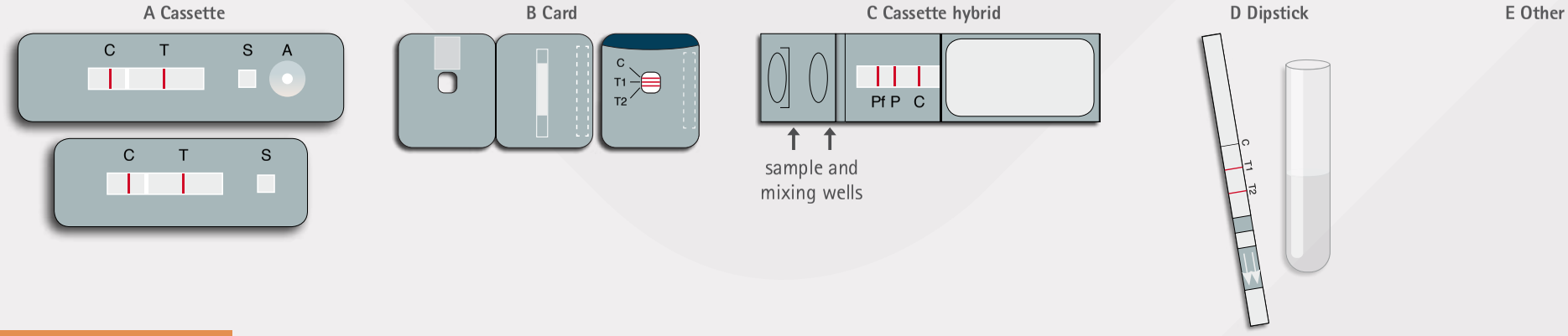
[a] pLDH, plasmodium lactate dehydrogenase; HRP2, histidine rich protein 2; pv, *P. vivax*; pf, *P. falciparum*

[b] Sequence when test held in a horizontal position and the sample well is at the far right and control line, far left

[c] Time from placement of buffer, or from 'intermediate' step, if applicable

[d] See Annex 2

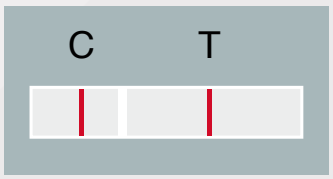
[e] Formats include: cassette (A); card (B); hybrid (C), dipstick (D); or other (E). Each product should ideally be accompanied by all required materials (lancet, pipette, etc.) particularly when used at the village health worker level; however, this is often not the case and the contents depend on the request of the procuring agent.



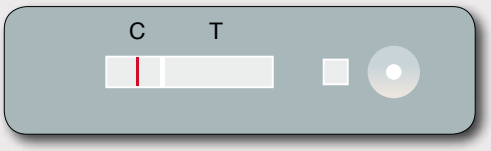
Annex 2: Malaria RDT guide to results interpretation

Type A: Malaria Generic Pf RDT Results Guide

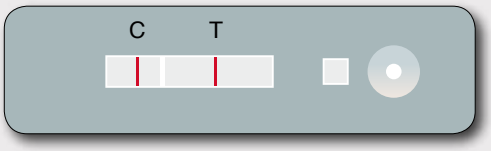
Results Window: C=control line; T=test line with bound HRP-2 or Pf-specific pLDH antibody.



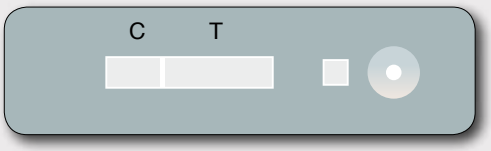
Negative Results: One line 'C' appears in the results window.

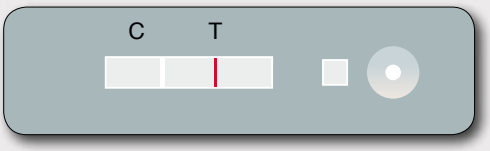


Positive Results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window.
Test is positive even if the test line is faint.



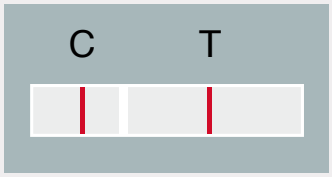
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



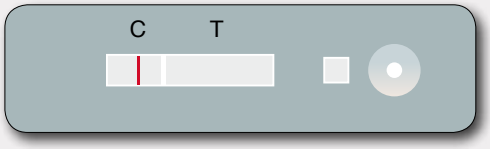


Type B: Malaria Generic Major Plasmodium species (pan) RDT Results Guide

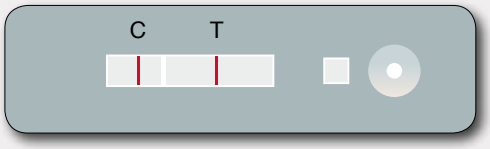
Results Window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



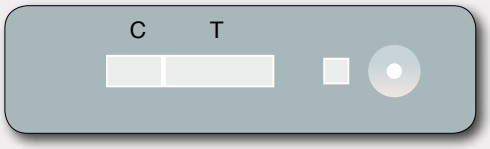
Negative Results: One line 'C' appears in the results window.

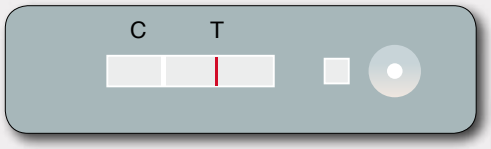


Positive Results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P.malariae*, *P.ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



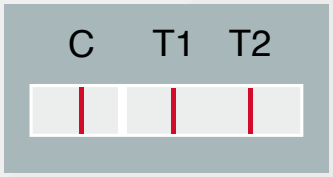
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



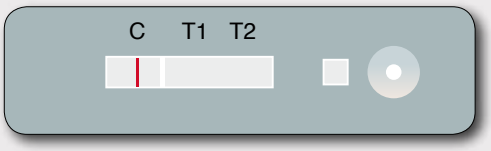


Type C: Malaria Generic Pan-Pf RDT Results Guide

Results Window: C=control line; T1=test line with bound pLDH or aldolase antibody; T2=test line with bound HRP2 and/or Pf specific pLDH antibody.

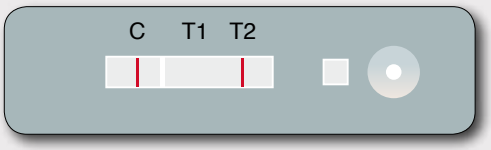


Negative Results: Only one line 'C' appears in the results window.

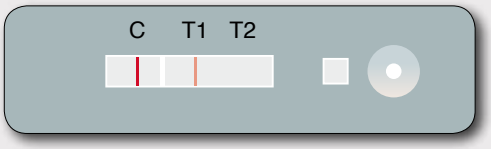


Positive Results:

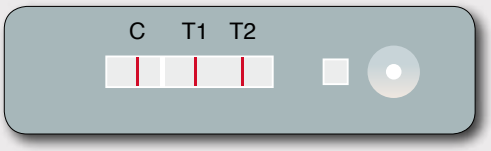
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



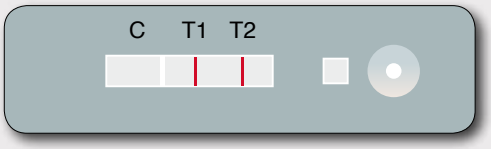
Non-falciparum infection (*P. vivax, P.ovale, P.malariae*) or mixed infection of these:
Two lines 'C' and 'T1" appear in the results window.

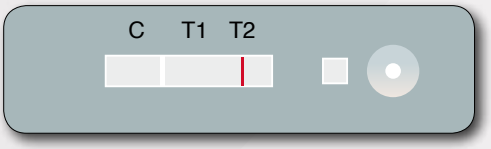


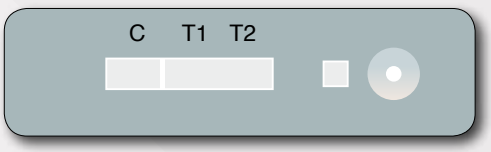
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

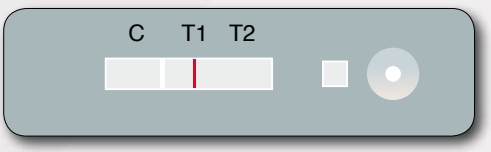


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



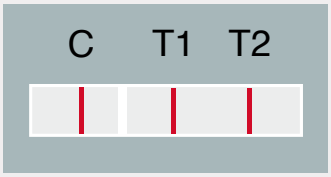




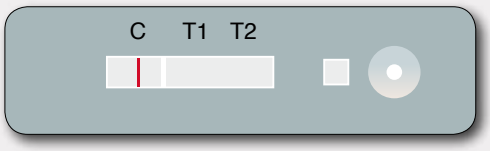


Type D: Malaria Generic Pf-Pan RDT Results Guide

Results Window: C=control line; T1=test line with bound HRP2 or Pf specific LDH antibody;
T2=test line with bound pLDH or aldolase antibody.

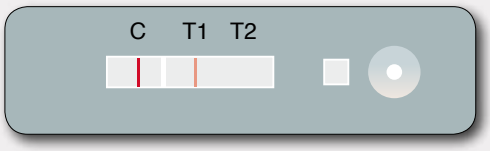


Negative Results: Only one line 'C' appears in the results window.

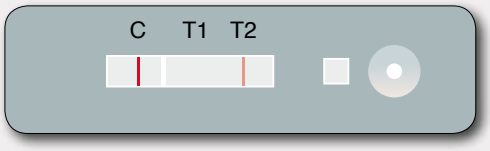


Positive Results:

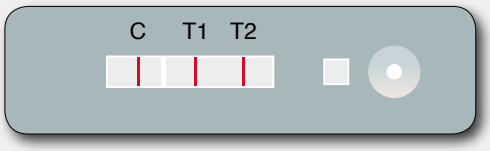
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



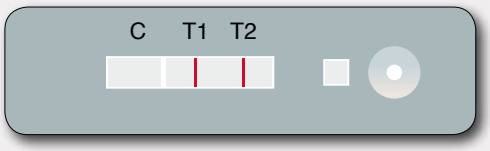
Non-falciparum infection (*P. vivax*, *P.ovale*, *P.malariae*) or mixed infection of these.
Two lines 'C' and 'T2' appear in the results window.

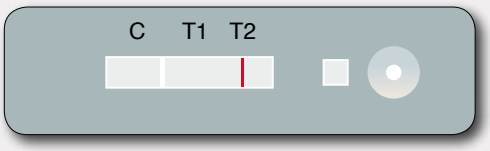


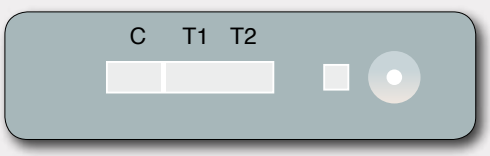
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

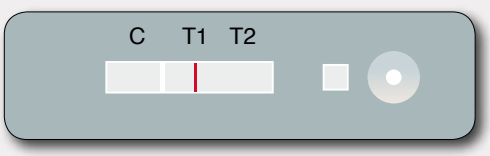


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



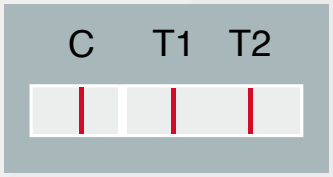




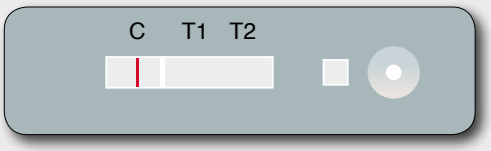


Type E: Malaria Generic Pv-Pf RDT Results Guide

Results Window: C=control line; T1=test line with bound *P. vivax* specific pLDH;
T2=test line with bound HRP2 or Pf-specific pLDH antibody.

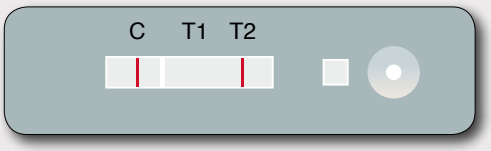


Negative Results: Only one line 'C' appears in the results window.

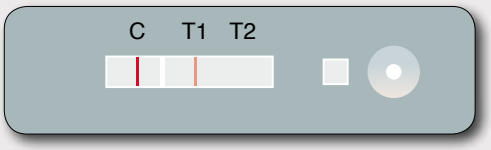


Positive Results:

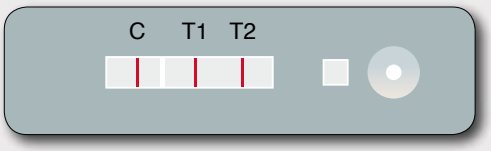
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



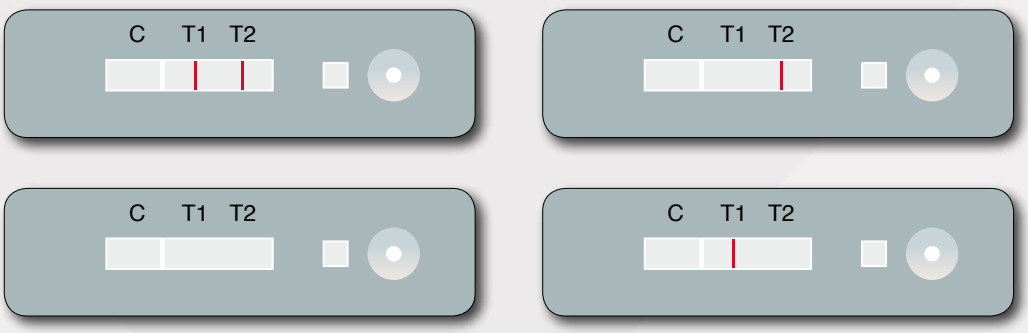
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

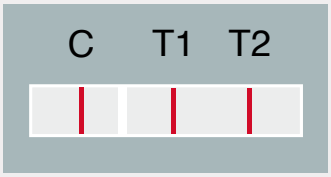


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

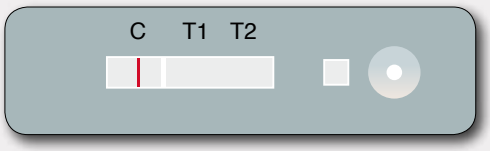


Type F: Malaria Generic Pf-Pv RDT Results Guide

Results Window: C=control line; T1= test line with bound HRP2 or Pf-specific pLDH antibody; T2=test line with bound *P. vivax* specific pLDH.

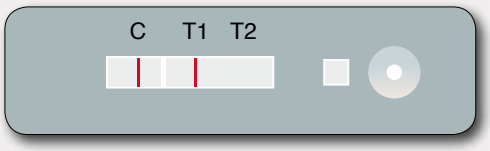


Negative Results: Only one line 'C' appears in the results window.

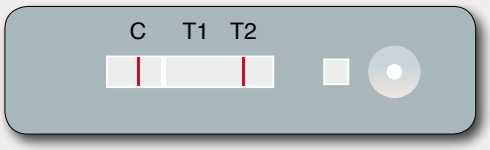


Positive Results:

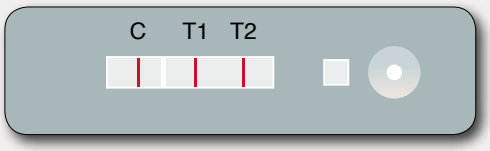
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



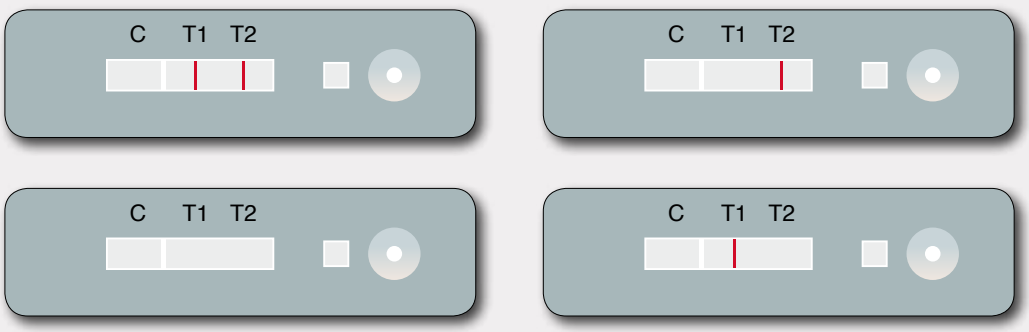
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

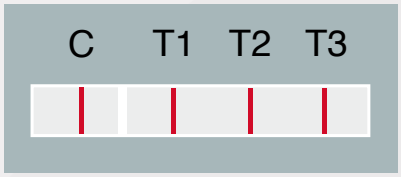


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

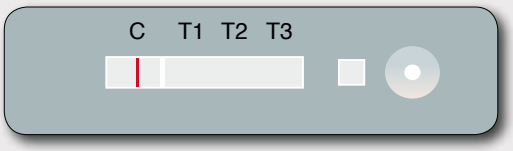


Type G: Malaria Generic Pan-Pv-Pf RDT Results Guide

Results Window: C=control line; T1=test line bound with pLDH or aldolase antibody; T2=test line with bound *P. vivax* specific pLDH; T3=test line with bound HRP2 or Pf-specific pLDH antibody

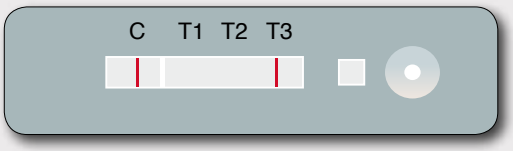


Negative Results: Only one line 'C' appears in the results window.

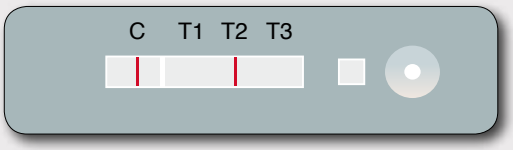


Positive Results:

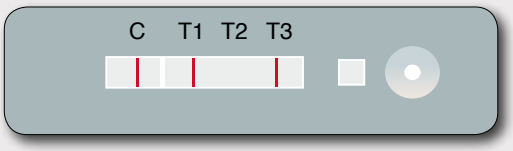
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



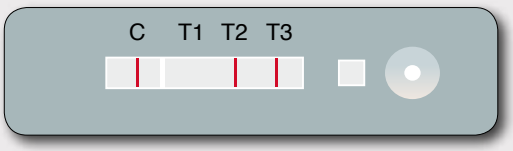
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



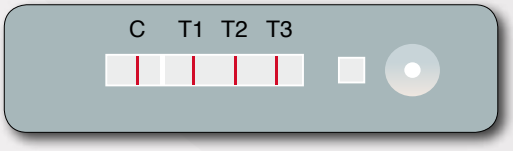
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



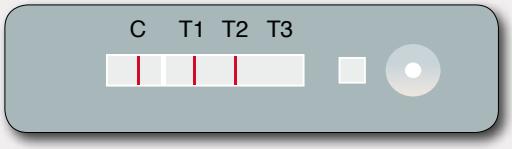
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



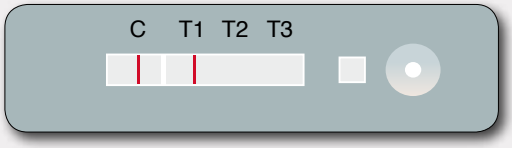
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



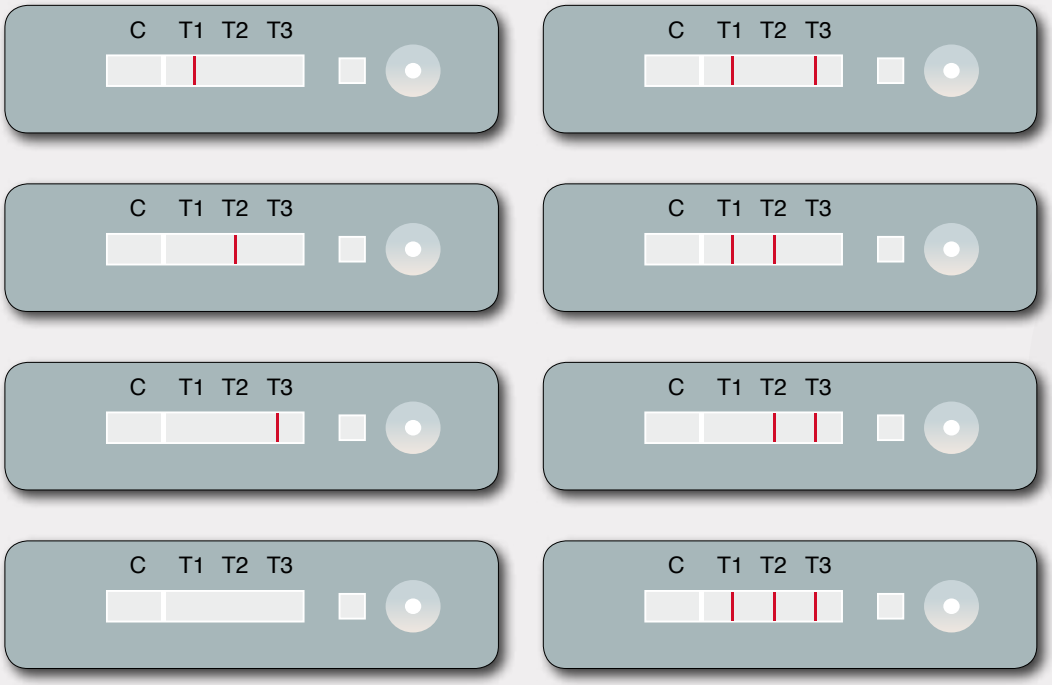
P. vivax with or without *P. ovale* and/or *P. malariae* infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



P. malariae and/or *P. ovale P. vivax* infection. Two lines 'C' and 'T1' appear in the results window.

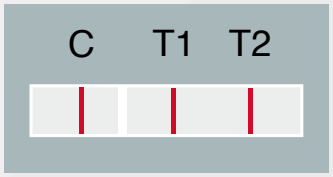


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

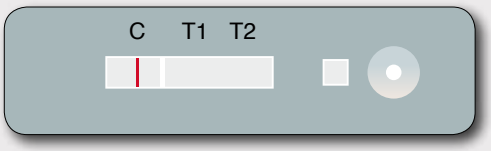


Type H: Malaria Generic VOM[1]-Pf RDT Results Guide

Results Window: C=control line; T1= test line bound with pLDH specific for non. *P. falciparum* (*P. vivax*, *P. ovale* and *P. malariae*); T2=test line with bound HRP2 or Pf-specific pLDH antibody

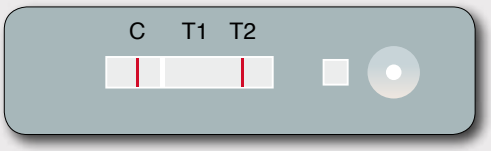


Negative Results: Only one line 'C' appears in the results window.

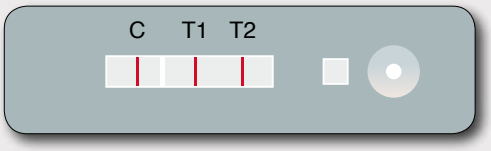


Positive Results:

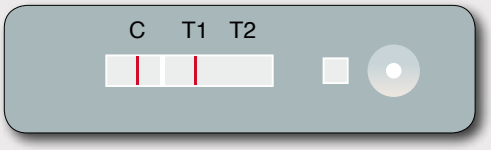
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



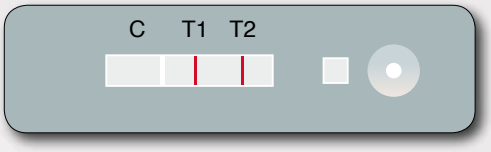
P. falciparum mixed infection (with anyone or more of *P. vivax*, *P. ovale* and *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

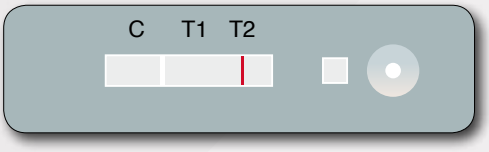


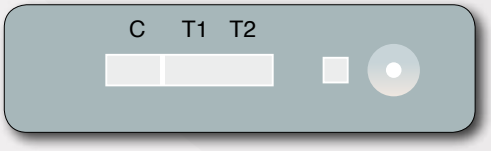
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection of these. Two lines 'C' and 'T1' appear in the results window.

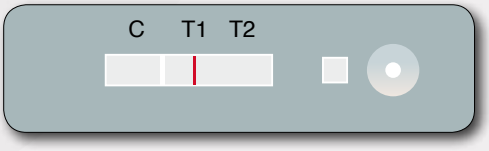


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.





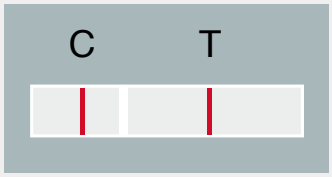




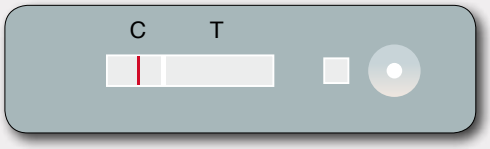
[1] VOM -*P. vivax, P. ovale, P. malariae*

Type I: Malaria Generic Pv RDT Results Guide

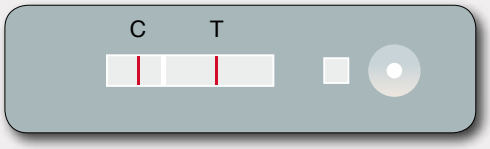
Results Window: C=control line; T=test line bound with *P. vivax* specific pLDH.



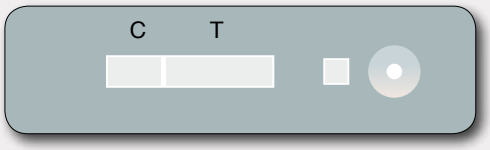
Negative Results: Only one line 'C' appears in the results window.

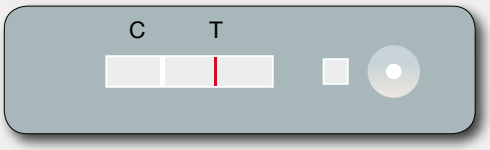


Positive Results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



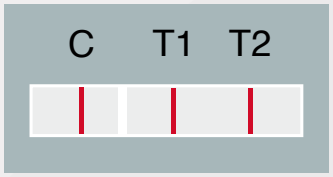
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



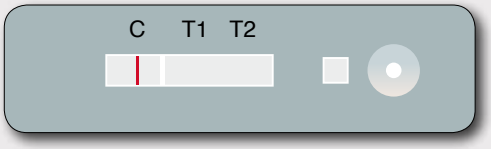


Type J: Malaria Generic Pf-Pf RDT Results Guide

Results Window: C=control line; T1= test line bound with pLDH specific for *P. falciparum*; T2=test line bound with HRP2.

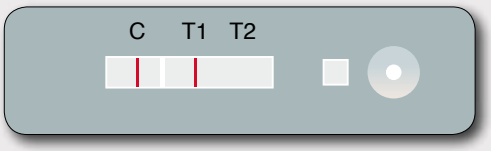


Negative Results: Only one line 'C' appears in the results window.

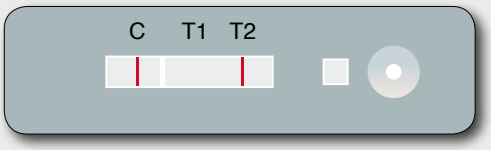


Positive Results:

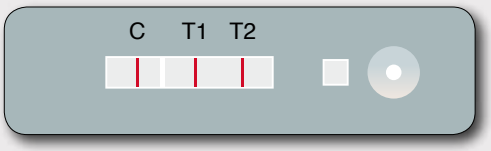
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



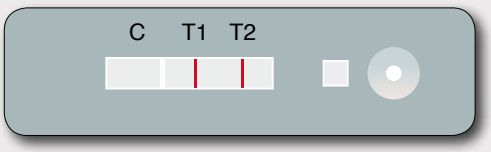
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.

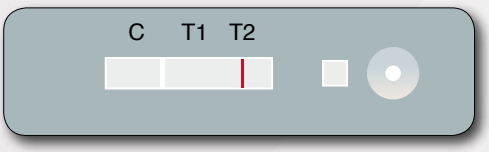


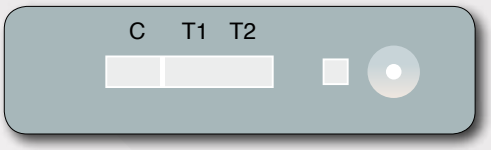
P. falciparum infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

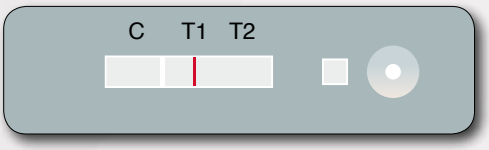


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



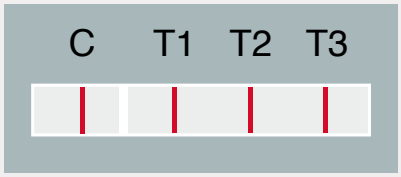




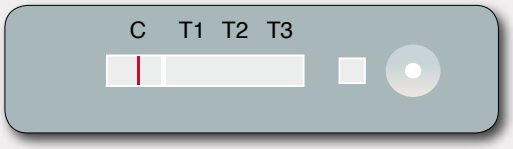


Type K: Malaria Generic Pv-Pf-Pf RDT Results Guide

Results Window: C=control line; T1= test line with bound *P. vivax*-specific pLDH; T2=test line with bound HRP2 or Pf-specific pLDH antibody; T3=test line with bound HRP2 or Pf-specific pLDH antibody. If an RDT has bound HRP2 antibodies on T2 then T3 will have bound Pf-specific-pLDH and vice versa (T2 Pf antigen target ≠ T3 Pf antigen target).

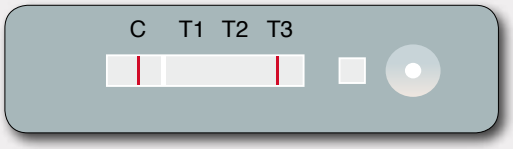


Negative Results: Only one line 'C' appears in the results window.

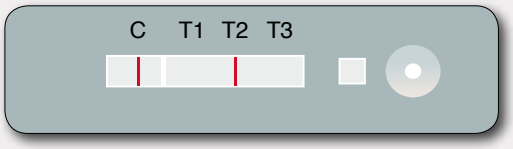


Positive Results:

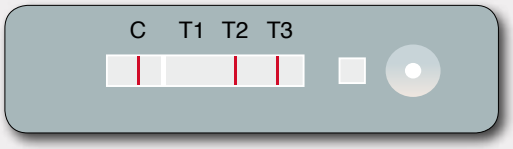
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



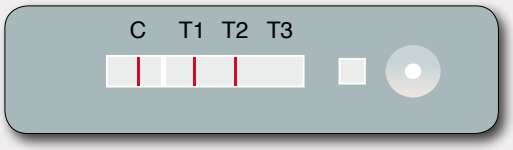
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



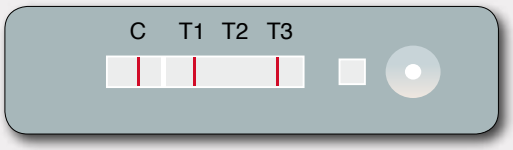
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



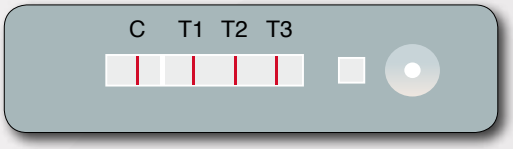
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



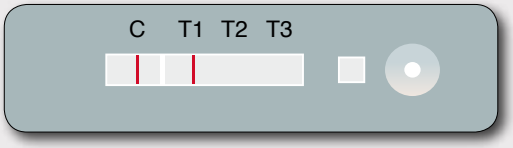
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T3' appear in the results window.



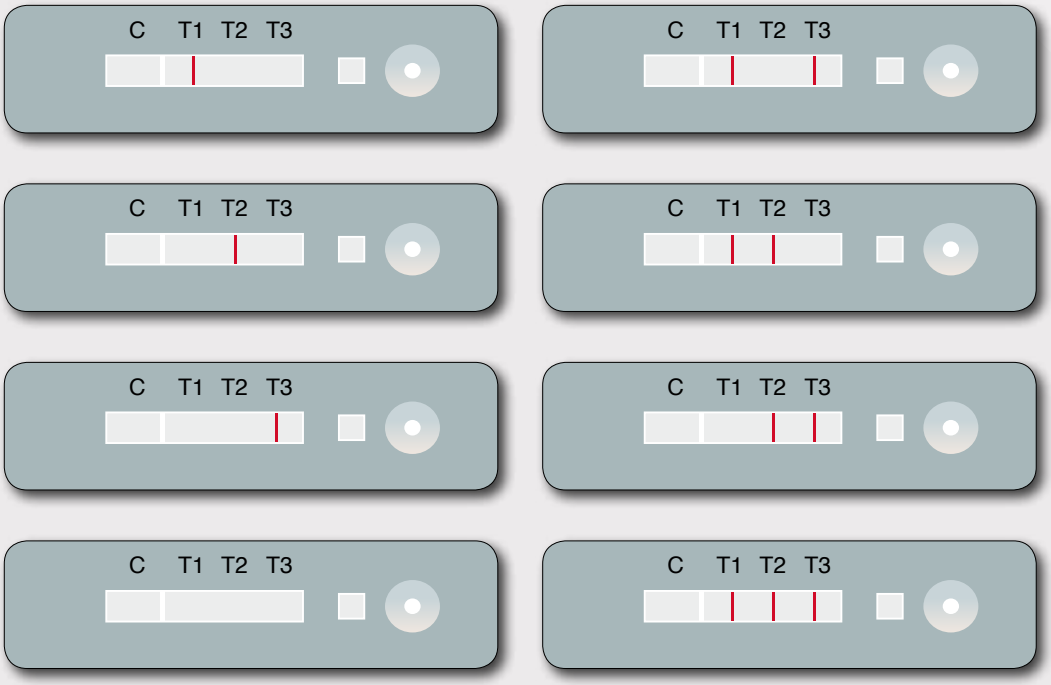
P. falciparum infection and *P. vivax* mixed infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



P. vivax infection. Two lines 'C' and 'T1' appear in the results window.

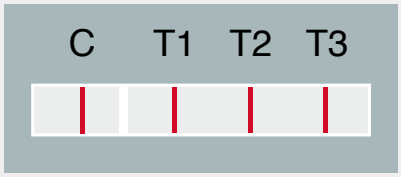


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

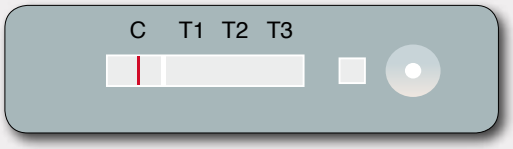


Type L: Malaria Generic Pan-Pf-Pf RDT Results Guide

Results Window: C=control line; T1= test line with bound PAN-pLDH or aldolase antibody; T2=test line with bound HRP2 or Pf-specific pLDH antibody; T3=test line with bound HRP2 or Pf-specific pLDH antibody . If an RDT has bound HRP2 antibodies on T2 then T3 will have bound Pf-specific-pLDH and vice versa (T2 Pf antigen target ≠ T3 Pf antigen target)

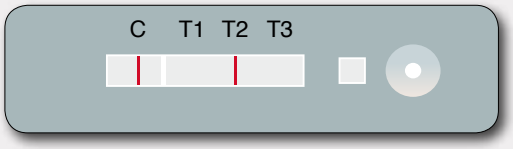


Negative Results: Only one line 'C' appears in the results window.

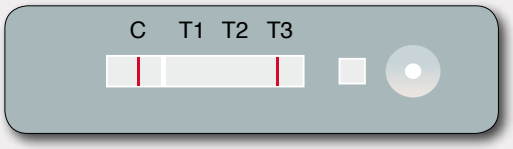


Positive Results:

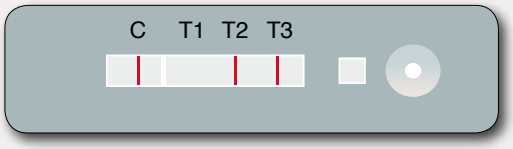
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



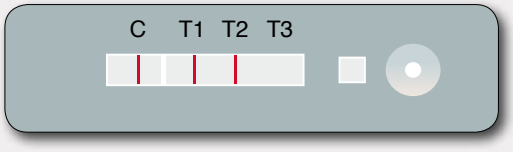
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



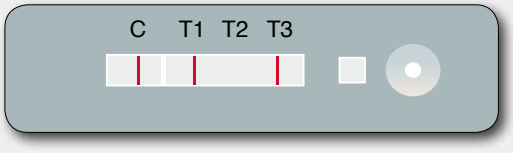
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



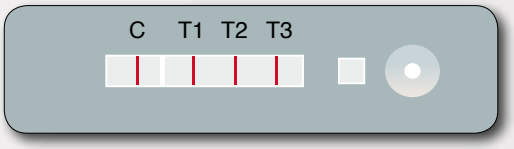
P. falciparum infection with or without mixed infection with any one or more of *P. vivax*, *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T2' appear in the results window.



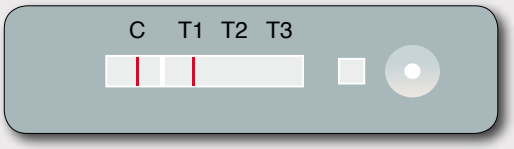
P. falciparum infection with or without mixed infection with any one or more of *P. vivax*, *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



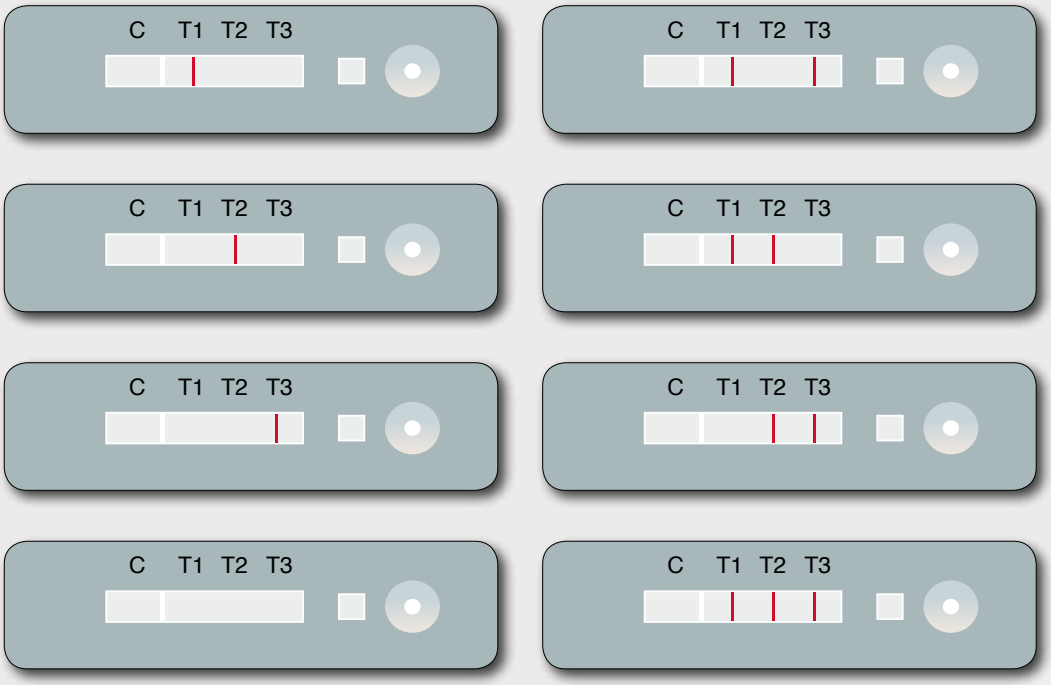
P. falciparum infection with or without mixed infection with any one or more of *P. vivax*, *P. ovale* or *P. malariae*.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



Non-P. falciparum infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection of these.
Two lines 'C' and 'T1' appear in the results window.



Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



Annex 3: Phase 1 results

TableA3.1: Lot variability in positive results[a] against Phase 1 *P. falciparum* culture samples at low (200) and high (2000) parasite density (parasites/µl)

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=20) Total positive results returned							
			200 parasites/µl						2000 parasites/µl	
			Lot 1			Lot 2			Lot 1	Lot 2
			Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2
Pf only										
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	7.0	6.0	5.0	9.0	9.0 (9)	7.0	19.0	20.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
ICT MALARIA P.F.	ML04	ICT INTERNATIONAL	4.0	2.0	0.0	4.0	1.0 (1)	0.0	16.0	18.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	14.0	13.0	13.0	15.0	17.0 (17)	15.0	20.0	20.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	20.0	17.0	17.0	17.0	18.0 (18)	17.0	20.0	20.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	19.0	17.0	17.0	18.0	19.0 (19)	18.0	20.0	20.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	16.0	17.0	16.0	19.0	19.0 (19)	19.0	19.0	19.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	19.0	19.0	19.0	19.0	17.0 (17)	17.0	20.0	20.0
Pf and Pan										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	19.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	15.0	16.0	13.0	15.0	14.0 (14)	12.0	20.0	20.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	18.0	18.0	17.0	20.0	20.0	20.0	20.0	20.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	18.0	18.0	17.0	20.0	19.0 (19)	19.0	20.0	20.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	18.0	18.0	17.0	18.0	18.0 (18)	18.0	20.0	20.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	19.0	19.0	19.0	19.0	19.0 (19)	19.0	20.0	20.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	10.0	13.0	10.0	11.0	12.0 (12)	11.0	18.0	20.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	16.0	15.0	14.0	16.0	14.0 (14)	14.0	20.0	20.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	19.0	18.0	18.0	18.0	17.0 (17)	17.0	20.0	20.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	18.0	19.0	17.0	20.0	18.0 (18)	18.0	20.0	20.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	14.0	17.0	13.0	17.0	16.0 (16)	16.0	20.0	20.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	17.0	16.0	16.0	16.0	16.0 (16)	15.0	20.0	20.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	19.0	19.0	19.0	20.0	18.0 (18)	18.0	20.0	20.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	20.0	20.0	20.0	20.0	20.0	20.0	19.0 (19)	20.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	19.0	19.0	19.0	18.0 (19)	19.0 (19)	18.0 (19)	20.0	19.0 (19)
Pf and Pv										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	20.0	20.0	20.0	17.0	20.0	17.0	20.0	20.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	20.0	20.0	20.0	19.0	20.0	19.0	20.0	19.0

Table A3.1 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=20) Total positive results returned							
			200 parasites/µl						2000 parasites/µl	
			Lot 1			Lot 2			Lot 1	Lot 2
			Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	19.0	18.0	17.0	20.0	19.0 (19)	19.0	19.0 (19)	20.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	14.0	13.0	12.0	11.0	10.0 (10)	9.0	19.0 (19)	20.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	12.0 (17)	16.0	12.0 (17)	18.0	16.0 (16)	16.0	20.0	20.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	20.0	20.0	20.0	17.0	20.0	17.0	20.0	20.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	15.0	14.0	14.0	14.0	13.0 (13)	12.0	20.0	19.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	18.0	14.0	14.0	18.0	20.0	18.0	20.0	20.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	20.0	20.0	20.0	17.0	20.0	17.0	20.0	20.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/PV TEST	MAL-PFV-0207	Hema Diagnostic Systems, LLC	4.0	3.0	1.0	0.0 (19)	0.0 (0)	0.0 (19)	9.0	0.0 (19)
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	19.0	20.0	19.0	20.0	19.0 (19)	19.0	20.0	20.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	18.0	17.0	17.0	19.0	19.0 (19)	18.0	19.0	20.0
Pan only										
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	18.0	19.0	17.0	17.0	11.0 (11)	11.0	20.0	20.0

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

[a] Results are based on the first readers interpretation according to manufacturers instructions.

[b] Number of samples that returned a positive result for both tests. Where one test was invalid and the other positive, positive agreement was recorded.

[c] Positive results presented in the table are based on a positive pf test line (either pf-HRP2 or pf-pLDH).

Table A3.2: Distribution of test band intensity (0–4) scores against Phase 1 *P. falciparum* cultured parasites at low (200) and high (2000) parasite densities (parasites/µl)

Product	Catalogue number	Manufacturer	200 parasites/µl					2000 parasites/µl					200 parasites/µl					2000 parasites/µl				
			Percentage distribution of Pf test band intensity[b] (n=80)					Percentage distribution of Pf test band intensity[b] (n=40)					Percentage distribution of Pan test band intensity[b] (n=80)					Percentage distribution of Pan test band intensity[b] (n=40)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf only																						
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	61.3	37.5	1.3	0.0	0.0	2.5	37.5	42.5	17.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	0.0	1.3	36.3	48.8	13.8	0.0	0.0	0.0	22.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	0.0	21.3	25.0	47.5	6.3	0.0	0.0	0.0	22.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA P.F.	ML04	ICT INTERNATIONAL	86.3	13.8	0.0	0.0	0.0	15.0	37.5	32.5	15.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	26.3	61.3	11.3	1.3	0.0	0.0	15.0	27.5	22.5	35.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	10.0	38.8	42.5	8.8	0.0	0.0	2.5	17.5	42.5	37.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	15.0	20.0	45.0	20.0	0.0	0.0	2.5	7.5	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	0.0	15.0	25.0	47.5	12.5	0.0	0.0	0.0	17.5	82.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	8.8	18.8	35.0	32.5	5.0	0.0	2.5	10.0	42.5	45.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	11.3	26.3	37.5	23.8	1.3	5.0	0.0	7.5	30.0	57.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	7.5	23.8	35.0	25.0	8.8	0.0	0.0	5.0	20.0	75.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																						
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	2.5	41.3	47.5	7.5	1.3	0.0	2.5	25.0	25.0	47.5	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	25.0	32.5	36.3	6.3	0.0	0.0	5.0	17.5	35.0	42.5	80.0	20.0	0.0	0.0	0.0	57.5	35.0	7.5	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	78.8	21.3	0.0	0.0	0.0	50.0	42.5	7.5	0.0	0.0	80.0	20.0	0.0	0.0	0.0	57.5	35.0	7.5	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	15.0	31.3	41.3	12.5	0.0	0.0	2.5	20.0	77.5	21.3	77.5	1.3	0.0	0.0	0.0	0.0	52.5	47.5	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	5.0	35.0	46.3	13.8	0.0	0.0	0.0	12.5	32.5	55.0	93.8	6.3	0.0	0.0	0.0	0.0	82.5	17.5	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	6.3	23.8	32.5	32.5	5.0	0.0	0.0	2.5	25.0	72.5	55.0	42.5	2.5	0.0	0.0	0.0	25.0	50.0	25.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	0.0	10.0	50.0	35.0	5.0	0.0	0.0	0.0	35.0	65.0	2.5	92.5	5.0	0.0	0.0	0.0	2.5	77.5	20.0	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	10.0	31.3	41.3	15.0	2.5	0.0	0.0	17.5	37.5	45.0	76.3	23.8	0.0	0.0	0.0	17.5	77.5	5.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	5.0	10.0	28.8	32.5	23.8	0.0	2.5	5.0	12.5	80.0	67.5	32.5	0.0	0.0	0.0	0.0	25.0	72.5	2.5	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	42.5	47.5	6.3	3.8	0.0	5.0	15.0	22.5	52.5	5.0	72.5	27.5	0.0	0.0	0.0	57.5	42.5	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	23.8	28.8	33.8	11.3	2.5	0.0	0.0	22.5	22.5	55.0	90.0	10.0	0.0	0.0	0.0	60.0	40.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	10.0	33.8	46.3	8.8	1.3	0.0	5.0	17.5	25.0	52.5	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	6.3	43.8	43.8	5.0	1.3	0.0	2.5	25.0	55.0	17.5	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	21.3	36.3	33.8	8.8	0.0	0.0	5.0	20.0	75.0	91.3	8.8	0.0	0.0	0.0	0.0	65.0	35.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	20.0	36.3	37.5	6.3	0.0	0.0	0.0	32.5	45.0	22.5	80.0	20.0	0.0	0.0	0.0	10.0	77.5	12.5	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	18.8	37.5	35.0	6.3	2.5	0.0	5.0	20.0	22.5	52.5	97.5	1.3	1.3	0.0	0.0	10.0	82.5	7.5	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	5.0	40.0	25.0	26.3	3.8	0.0	2.5	7.5	27.5	62.5	96.3	3.8	0.0	0.0	0.0	0.0	82.5	17.5	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	22.5	30.0	45.0	2.5	0.0	0.0	0.0	30.0	70.0	8.8	88.8	2.5	0.0	0.0	2.5	0.0	52.5	45.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	6.3	17.5	22.5	32.5	21.3	2.5	2.5	0.0	17.5	77.5	43.8	53.8	0.0	2.5	0.0	5.0	7.5	65.0	22.5	0.0

Table A3.2 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µl					2000 parasites/µl					200 parasites/µl					2000 parasites/µl				
			Percentage distribution of Pf test band intensity[b] (n=80)					Percentage distribution of Pf test band intensity[b] (n=40)					Percentage distribution of Pan test band intensity[b] (n=80)					Percentage distribution of Pan test band intensity[b] (n=40)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf and Pv																						
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	3.8	27.5	22.5	41.3	5.0	0.0	0.0	0.0	32.5	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	1.3	30.0	17.5	32.5	18.8	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	1.3	22.5	35.0	36.3	5.0	2.5	0.0	2.5	32.5	62.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	1.3	30.0	16.3	36.3	16.3	0.0	0.0	0.0	12.5	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	32.5	17.5	35.0	15.0	0.0	0.0	0.0	12.5	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	5.0	32.5	41.3	16.3	5.0	0.0	0.0	7.5	27.5	65.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.0	46.3	12.5	1.3	0.0	2.5	15.0	22.5	57.5	2.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	22.5	31.3	33.8	10.0	2.5	0.0	0.0	25.0	25.0	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	3.8	27.5	22.5	41.3	5.0	0.0	0.0	0.0	32.5	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	1.3	30.0	17.5	32.5	18.8	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	30.0	45.0	18.8	6.3	0.0	2.5	10.0	17.5	25.0	45.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	12.5	36.3	35.0	15.0	1.3	0.0	0.0	25.0	25.0	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	3.8	27.5	22.5	41.3	5.0	0.0	0.0	0.0	32.5	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	1.3	30.0	17.5	32.5	18.8	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RAPID 1-2-3® HEMA EXPRESS® MALARIA PF/PV TEST	MAL-PFV-0207	Hema Diagnostic Systems, LLC	91.3	3.8	5.0	0.0	0.0	77.5	12.5	5.0	2.5	2.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	26.3	22.5	47.5	3.8	0.0	0.0	2.5	25.0	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	2.5	18.8	22.5	32.5	23.8	0.0	0.0	0.0	22.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	70.0	30.0	0.0	0.0	0.0	0.0	15.0	77.5	7.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	8.8	31.3	45.0	13.8	1.3	2.5	0.0	12.5	27.5	57.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pan only																						
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	18.8	35.0	31.3	13.8	1.3	0.0	7.5	12.5	35.0	45.0

NA, not applicable

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

[a] Denotes no band visible

[b] Calculations include invalid tests

[c] Results presented in the table are based on band intensity of a pf-HRP2 line

[d] Results presented in the table are based on band intensity of a pf-pLDH line

Annex 4: Phase 2 results

TableA4.1: Lot variability in positive results against Phase 2 wild type *P. falciparum* and *P. vivax* samples at low (200) and high (2000) parasite density (parasites/µl)

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=98) Total positive results[a] returned								*P. vivax* samples (n=34) Total positive results[a] returned							
			200 parasites/µl						2000[b] parasites/µl		200 parasites/µl						2000[b] parasites/µl	
			Lot 1			Lot 2			Lot 1	Lot 2	Lot 1			Lot 2			Lot 1	Lot 2
			Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2
Pf only																		
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	48.0	52.0	41.0	53.0	53.0	45.0	97.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	97.0 (97)	97.0 (97)	96.0 (96)	98.0	97.0	97.0	97.0 (97)	97.0 (97)	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	96.0	95.0	94.0	97.0	95.0	95.0	98.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	79.0	69.0	66.0	78.0	79.0	70.0	97.0 (97)	97.0	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	92.0	92.0	89.0	95.0	90.0	89.0	96.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	96.0	94.0	93.0	98.0	97.0	97.0	97.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	97.0	98.0	97.0	96.0	97.0	95.0	98.0	96.0	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	89.0	92.0	87.0	86.0	85.0	76.0	97.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	90.0	89.0 (97)	88.0 (97)	93.0	90.0	90.0	98.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	94.0	91.0	91.0	91.0	92.0	90.0	97.0	98.0	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																		
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	90.0	88.0	86.0	90.0	92.0	87.0	98.0	98.0	5.0	2.0	2.0	4.0	2.0	2.0	34.0	33.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	76.0	73.0	71.0	74.0	74.0 (96)	69.0 (96)	97.0	97.0	0.0	2.0	0.0	0.0	1.0	0.0	32.0	31.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	97.0	98.0	97.0	98.0	97.0	97.0	98.0	98.0	17.0	20.0	10.0	27.0	26.0	22.0	15.0	24.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	82.0 (97)	80.0	77.0 (97)	89.0	87.0	85.0	97.0	98.0	12.0	12.0	8.0	7.0	10.0	6.0	34.0	32.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	90.0	92.0	89.0	91.0	92.0	89.0	98.0	98.0	30.0	31.0	27.0	30.0	27.0	26.0	34.0	34.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	98.0	98.0	98.0	98.0	98.0	98.0	98.0	98.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	1.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	89.0	87.0	86.0	80.0	82.0	76.0	96.0 (97)	97.0	17.0	10.0	7.0	5.0	5.0	4.0	32.0	32.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	94.0	96.0	93.0	97.0	96.0	96.0	98.0	98.0	30.0	29.0	27.0	31.0	29.0	27.0	30.0	33.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	54.0	48.0	43.0	56.0	53.0	49.0	94.0	94.0	5.0	7.0	3.0	4.0	8.0	2.0	33.0	34.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	72.0	72.0	67.0	76.0	70.0	69.0	98.0	98.0	3.0	3.0	2.0	4.0	2.0 (33)	1.0 (33)	31.0	31.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	91.0	94.0	91.0	95.0 (97)	88.0	86.0 (97)	98.0	98.0	1.0	2.0	1.0	0.0	1.0	0.0	30.0	29.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	82.0	85.0	78.0	82.0	85.0 (97)	77.0 (97)	97.0	98.0	1.0	1.0	1.0	1.0	1.0	1.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	95.0	96.0	95.0	96.0	93.0	92.0	98.0	98.0	34.0	34.0	34.0	34.0	33.0	33.0	34.0	34.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	80.0	79.0	75.0	84.0	85.0	82.0	97.0	97.0	33.0	33.0	32.0	31.0	34.0	31.0	33.0	34.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	83.0	82.0	79.0	86.0	85.0	82.0	98.0	98.0	29.0	26.0	24.0	30.0	32.0	28.0	34.0	32.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	89.0	90.0	87.0	94.0	89.0	89.0	97.0	98.0	34.0	30.0	30.0	32.0	34.0	32.0	34.0	30.0 (33)
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	97.0 (97)	98.0	97.0 (97)	98.0	97.0	97.0	98.0	98.0	18.0	22.0	14.0	25.0	30.0	22.0	18.0	16.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	94.0	93.0	92.0	92.0 (96)	92.0 (93)	86.0 (91)	98.0	97.0 (97)	34.0	34.0	34.0	31.0 (31)	29.0 (31)	26.0 (28)	34.0	33.0 (33)

Table A4.1 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=98) Total positive results[a] returned								*P. vivax* samples (n=34) Total positive results[a] returned							
			200 parasites/µl						2000[b] parasites/µl		200 parasites/µl						2000[b] parasites/µl	
			Lot 1			Lot 2			Lot 1	Lot 2	Lot 1			Lot 2			Lot 1	Lot 2
			Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2
Pf and Pv																		
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	93.0	93.0	91.0	95.0	92.0	91.0	98.0	98.0	33.0	34.0	33.0	34.0	33.0	33.0	34.0	34.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	94.0	91.0	90.0	96.0	91.0	91.0	98.0	98.0	33.0	34.0	33.0	33.0	33.0	32.0	34.0	34.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	98.0	96.0	96.0	97.0	97.0	97.0	98.0	98.0	34.0	34.0	34.0	33.0	31.0	30.0	34.0	34.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	93.0	93.0 (97)	91.0 (97)	93.0	91.0	91.0	98.0	98.0	34.0	33.0	33.0	32.0	29.0	28.0	34.0	32.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	93.0	95.0	93.0	91.0	91.0	89.0	98.0	98.0	32.0	33.0	32.0	32.0	29.0	28.0	34.0	31.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	94.0	93.0	92.0	98.0	95.0	95.0	98.0	98.0	34.0	34.0	34.0	34.0	34.0	34.0	34.0	34.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	59.0	51.0	47.0	57.0	50.0	48.0	94.0	94.0	0.0	0.0	0.0	2.0	4.0	1.0	7.0	9.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	75.0	74.0	70.0	71.0	73.0	66.0	92.0 (97)	96.0	2.0	0.0	0.0	1.0	2.0 (33)	0.0 (33)	17.0	16.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	93.0	93.0	91.0	95.0	92.0	91.0	98.0	98.0	33.0	34.0	33.0	34.0	33.0	33.0	34.0	34.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	94.0	91.0	90.0	96.0	91.0	91.0	98.0	98.0	33.0	34.0	33.0	33.0	33.0	32.0	34.0	34.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	65.0	70.0	61.0	64.0	63.0	58.0	95.0	95.0	1.0	2.0	1.0	1.0	3.0	1.0	32.0	33.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	88.0	82.0	81.0	85.0	89.0	83.0	98.0	98.0	34.0	34.0	34.0	34.0	34.0	34.0	34.0	34.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	93.0	93.0	91.0	95.0	92.0	91.0	98.0	98.0	33.0	34.0	33.0	34.0	33.0	33.0	34.0	34.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	94.0	91.0	90.0	96.0	91.0	91.0	98.0	98.0	33.0	34.0	33.0	33.0	33.0	32.0	34.0	34.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	M A L - P F V - CAS/25(100)	Hema Diagnostic Systems, LLC	95.0	96.0	95.0	94.0	93.0	91.0	98.0	98.0	32.0	30.0	28.0	33.0	32.0	31.0	34.0	34.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	98.0	97.0	97.0	95.0	98.0	95.0	98.0	98.0	34.0	34.0	34.0	33.0	34.0	33.0	34.0	34.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	91.0	88.0	87.0	91.0	91.0	89.0	96.0 (97)	97.0 (97)	18.0 (33)	17.0	14.0 (33)	24.0	27.0	22.0	33.0 (33)	34.0
Pan only																		
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	78.0	72.0	70.0	75.0	69.0	66.0	97.0	98.0	3.0	1.0	1.0	4.0	1.0	0.0	24.0	24.0

NA, not applicable

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

[a] Results are based on the first readers interpretation according to manufacturers instructions.

[b] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[c] Number of samples that returned a positive result for both tests. Where one test was invalid and the other positive, positive agreement was recorded.

[d] Results presented in the table are based on a positive pf test line (either pf-HRP2 or pf-pLDH).

Table A4.2: Distribution of test band intensity (0–4) scores against Phase 2 wild type *P. falciparum* samples at low (200) and high (2000) parasite densities (parasites/µl)

Product	Catalogue number	Manufacturer	200 parasites/µl Percentage distribution of Pf test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of Pf test band intensity[c] (n=196)					200 parasites/µl Percentage distribution of pan test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of pan test band intensity[c] (n=196)					200 parasites/µl Percentage distribution of Pv test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of Pv test band intensity[c] (n=196)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf only																																
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	47.5	34.4	17.6	0.5	0.0	0.5	12.2	43.9	34.7	8.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	0.8	4.3	32.7	38.0	24.2	0.5	0.5	5.1	9.2	84.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	2.3	11.2	41.6	26.8	18.1	0.0	0.0	4.1	13.8	82.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	22.2	40.8	28.3	7.9	0.8	1.0	4.6	12.2	30.1	52.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	5.9	18.4	49.0	21.7	5.1	1.0	1.0	12.2	30.1	55.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1.8	7.9	28.1	35.0	27.3	0.5	0.0	1.5	10.2	87.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	1.0	5.6	31.9	33.2	28.3	1.0	0.0	2.0	7.7	89.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	10.2	19.4	37.0	23.5	10.0	0.5	1.5	14.3	21.4	62.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	7.7	18.4	43.4	21.9	8.7	0.0	2.0	5.6	20.4	71.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	6.1	12.2	39.8	26.3	15.6	0.5	0.5	4.1	12.8	82.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																																
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	8.2	24.2	44.6	17.9	5.1	0.0	1.5	10.7	32.7	55.1	96.9	1.0	2.0	0.0	0.0	76.0	19.4	4.6	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	24.5	32.1	28.6	12.5	2.3	1.0	3.1	14.3	35.7	45.9	98.5	1.5	0.0	0.0	0.0	66.3	19.9	13.8	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[e]	MFV-124F	AZOG, INC.	90.8	7.1	2.0	0.0	0.0	50.5	28.6	20.9	0.0	0.0	98.5	1.5	0.0	0.0	0.0	66.3	19.9	13.8	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.5	6.9	44.6	33.9	14.0	0.0	0.0	3.6	19.9	76.5	40.8	39.8	18.6	0.8	0.0	2.0	4.1	49.0	37.8	7.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	13.8	22.2	39.5	20.9	3.6	0.5	3.1	9.2	24.5	62.8	85.7	14.3	0.0	0.0	0.0	10.2	37.8	40.3	11.7	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	6.9	16.3	41.1	25.0	10.7	0.0	0.0	6.6	17.9	75.5	60.2	34.2	5.6	0.0	0.0	3.1	11.7	51.5	28.6	5.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	0.0	5.4	45.2	36.2	13.3	0.0	0.0	4.1	13.3	82.7	1.5	74.0	24.2	0.3	0.0	1.0	4.1	47.5	38.3	9.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	13.8	16.1	38.3	23.5	8.4	1.5	1.0	10.2	15.3	71.9	80.1	15.6	3.1	1.0	0.3	24.5	38.8	28.1	8.7	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	2.3	7.1	30.1	32.7	27.8	0.0	0.0	3.6	8.2	88.3	62.8	29.1	8.2	0.0	0.0	6.1	17.9	48.0	25.5	2.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	46.2	19.9	26.3	6.4	1.3	4.1	4.6	27.6	45.4	18.4	94.6	4.6	0.8	0.0	0.0	52.6	31.6	15.8	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	26.0	25.8	31.4	13.8	3.1	0.0	6.1	15.3	32.7	45.9	96.7	3.3	0.0	0.0	0.0	54.6	29.6	14.8	1.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	5.9	15.3	51.3	21.9	5.6	0.0	0.5	9.7	28.1	61.7	99.2	0.5	0.3	0.0	0.0	58.7	31.1	10.2	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	14.8	33.9	43.6	7.4	0.3	0.5	3.6	23.5	54.6	17.9	97.2	0.0	1.8	1.0	0.0	91.8	5.1	1.0	2.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	3.1	7.4	29.9	40.8	18.9	0.0	0.0	3.6	13.3	83.2	57.4	33.4	9.2	0.0	0.0	2.0	14.8	50.5	30.1	2.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	16.3	30.6	38.3	13.5	1.3	1.0	3.1	17.9	34.7	43.4	90.3	9.7	0.0	0.0	0.0	13.8	50.0	34.7	1.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	14.3	22.2	40.3	18.6	4.6	0.0	2.6	9.7	21.4	66.3	78.6	15.8	5.4	0.3	0.0	7.7	26.5	46.4	15.3	4.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	7.7	14.8	46.7	21.7	9.2	0.5	0.5	8.2	17.4	73.5	68.6	24.0	7.4	0.0	0.0	2.0	18.4	61.7	12.8	5.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.2 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µl Percentage distribution of Pf test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of Pf test band intensity[c] (n=196)					200 parasites/µl Percentage distribution of pan test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of pan test band intensity[c] (n=196)					200 parasites/µl Percentage distribution of Pv test band intensity[c] (n=392)					2000[b] parasites/µl Percentage distribution of Pv test band intensity[c] (n=196)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.3	8.7	40.1	34.2	16.8	0.0	0.0	3.6	9.7	86.7	38.8	41.8	19.1	0.3	0.0	1.0	5.1	41.8	39.8	12.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	5.1	6.4	24.5	28.1	36.0	0.5	0.0	2.0	6.6	90.8	38.5	37.0	21.4	2.8	0.3	1.5	3.1	31.6	35.2	28.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																																
CareStart™ Malaria HRP2/pLDH (Pf/ Pv) COMBO	G0161	Access Bio, Inc.	4.9	12.2	29.6	30.1	23.2	0.0	0.5	4.6	5.1	89.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.0	1.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/ VOM) COMBO	G0171	Access Bio, Inc.	5.1	8.7	27.6	28.8	29.9	0.0	0.5	3.6	4.6	91.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	1.0	8.2	40.3	30.6	19.9	0.0	0.0	4.6	7.7	87.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.2	0.0	0.8	0.0	0.0	100.0	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	5.6	9.2	32.1	28.6	24.5	0.0	0.0	5.6	12.8	81.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.0	0.3	0.0	0.0	99.5	0.0	0.5	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	5.6	11.2	30.1	28.8	24.2	0.0	0.0	3.6	14.3	82.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	99.5	0.0	0.5	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	3.1	15.3	40.6	24.7	16.3	0.0	0.5	4.1	13.8	81.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.5	0.0	0.0	0.0	99.5	0.0	0.5	0.0	0.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	44.6	20.4	27.6	5.6	1.8	4.1	5.6	23.0	48.5	18.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.2	0.8	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	25.3	24.7	36.0	11.0	3.1	3.6	5.6	18.4	32.7	39.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.5	0.0	0.0	0.0	96.9	2.6	0.5	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	4.9	12.2	29.6	30.1	23.2	0.0	0.5	4.6	5.1	89.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.0	1.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	5.1	8.7	27.6	28.8	29.9	0.0	0.5	3.6	4.6	91.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	33.2	31.4	26.3	7.7	1.5	3.1	3.1	21.4	28.6	43.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	12.2	25.8	43.6	16.8	1.5	0.0	3.6	10.7	33.2	52.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.5	1.3	0.3	0.0	0.0	98.0	1.0	1.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	4.9	12.2	29.6	30.1	23.2	0.0	0.5	4.6	5.1	89.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.0	1.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	5.1	8.7	27.6	28.8	29.9	0.0	0.5	3.6	4.6	91.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	3.6	6.9	40.6	29.6	19.4	0.0	0.0	4.1	8.2	87.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	1.0	7.4	20.2	30.6	40.8	0.0	0.0	1.5	4.6	93.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.5	0.0	0.0	0.0	0.5
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[e]	05FK100	Standard Diagnostics Inc.	54.9	30.1	14.5	0.5	0.0	2.0	4.6	39.3	35.7	18.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.7	0.3	0.0	0.0	0.0	99.5	0.0	0.0	0.0	0.5
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	7.9	19.1	48.2	20.4	4.3	1.0	3.1	8.7	28.1	59.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	86.7	12.2	1.0	0.0	0.0	84.2	15.3	0.5	0.0	0.0
Pan only																																
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0	28.8	35.7	9.2	1.3	0.5	3.1	15.8	35.2	45.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Denotes no visible band

[b] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[c] Calculations include invalid tests

[d] Results presented in the table are based on band intensity of a pf-HRP2 line

[e] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.3: Distribution of Pan/Pv test band intensity (0–4) scores for Phase 2 wild type *P. vivax* samples at low (200) and high (2000) parasite densities (parasites/µl)

Product	Catalogue number	Manufacturer	200 parasites/µl					2000[b] parasites/µl					200 parasites/µl					2000[b] parasites/µl				
			Percentage distribution of Pan test band intensity[c] (n=136)					Percentage distribution of Pan test band intensity[c] (n=68)					Percentage distribution of Pv test band intensity[c] (n=136)					Percentage distribution of Pv test band intensity[c] (n=68)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf only																						
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																						
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	90.4	9.6	0.0	0.0	0.0	1.5	26.5	61.8	10.3	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	95.6	3.7	0.0	0.7	0.0	7.4	33.8	52.9	4.4	1.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	16.9	73.5	8.1	1.5	0.0	0.0	1.5	32.4	66.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	68.4	27.2	3.7	0.7	0.0	2.9	8.8	52.9	29.4	5.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	11.8	47.1	37.5	3.7	0.0	0.0	0.0	7.4	41.2	51.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	0.0	11.0	79.4	9.6	0.0	0.0	0.0	1.5	41.2	57.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	72.1	21.3	4.4	2.2	0.0	5.9	8.8	63.2	20.6	1.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	10.3	43.4	44.1	2.2	0.0	1.5	1.5	7.4	50.0	39.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	81.6	13.2	5.1	0.0	0.0	1.5	39.7	48.5	7.4	2.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	91.2	8.8	0.0	0.0	0.0	8.8	27.9	58.8	4.4	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	97.1	2.2	0.7	0.0	0.0	11.8	41.2	45.6	1.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	97.1	0.0	2.9	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.7	40.4	54.4	4.4	0.0	0.0	0.0	1.5	45.6	52.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	3.7	53.7	40.4	2.2	0.0	0.0	0.0	13.2	70.6	16.2	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	14.0	45.6	39.0	1.5	0.0	2.9	1.5	5.9	35.3	54.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	4.4	40.4	54.4	0.7	0.0	2.9	0.0	10.3	51.5	35.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	14.7	75.0	10.3	0.0	0.0	0.0	0.0	13.2	86.8	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	5.9	8.1	59.6	22.1	4.4	1.5	0.0	0.0	5.9	92.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																						
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.5	13.2	68.4	15.4	1.5	0.0	0.0	1.5	22.1	76.5
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.2	20.6	66.9	10.3	0.0	0.0	0.0	1.5	47.1	51.5
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.9	30.9	64.0	2.2	0.0	0.0	0.0	1.5	35.3	63.2

Table A4.3 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µl					2000[b] parasites/µl					200 parasites/µl					2000[b] parasites/µl				
			Percentage distribution of Pan test band intensity[c] (n=136)					Percentage distribution of Pan test band intensity[c] (n=68)					Percentage distribution of Pv test band intensity[e] (n=136)					Percentage distribution of Pv test band intensity[e] (n=68)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	5.9	14.7	68.4	10.3	0.7	2.9	1.5	7.4	29.4	58.8
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.4	19.9	68.4	4.4	0.0	4.4	0.0	11.8	57.4	26.5
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	4.4	72.8	21.3	1.5	0.0	0.0	0.0	39.7	60.3
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	95.6	0.7	2.9	0.7	0.0	76.5	13.2	1.5	0.0	8.8
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	96.3	3.7	0.0	0.0	0.0	51.5	44.1	4.4	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.5	13.2	68.4	15.4	1.5	0.0	0.0	1.5	22.1	76.5
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.2	20.6	66.9	10.3	0.0	0.0	0.0	1.5	47.1	51.5
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	94.9	5.2	0.0	0.0	0.0	4.4	42.7	48.5	4.4	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	40.4	55.9	3.7	0.0	0.0	0.0	4.4	67.7	27.9
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.5	13.2	68.4	15.4	1.5	0.0	0.0	1.5	22.1	76.5
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.2	20.6	66.9	10.3	0.0	0.0	0.0	1.5	47.1	51.5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6.6	41.9	48.5	2.9	0.0	0.0	0.0	7.4	39.7	52.9
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.7	9.6	64.7	16.9	8.1	0.0	0.0	0.0	2.9	97.1
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	36.8	49.3	13.2	0.7	0.0	1.5	4.4	66.2	27.9	0.0
Pan only																						
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	93.4	5.1	1.5	0.0	0.0	29.4	35.3	30.9	4.4	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Denotes no visible band

[b] 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[c] Pan test line

[d] *P. vivax* test line

[e] Calculations include invalid tests

TableA4.4: Panel detection score of Phase 2 wild type *P. falciparum* at low (200) and high (2000) parasite densities (parasites/µl) by continent

Product	Catalogue number	Manufacturer	200 parasites/µl Panel detection score[a] by continent of sample origin			2000[b] parasites/µl Panel detection score[a] by continent of sample origin		
			Africa (n=57)	Asia (n=24)	South America (n=17)	Africa (n=57)	Asia (n=24)	South America (n=17)
Pf only								
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	33.3	33.3	29.4	98.3	100.0	100.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	86.0	100.0	94.1	100.0	100.0	100.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	80.7	100.0	94.1	100.0	100.0	100.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	91.2	100.0	100.0	100.0	100.0	100.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	82.5	87.5	88.2	100.0	100.0	100.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	43.9	62.5	52.9	94.7	100.0	94.1
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	68.4	75.0	70.6	100.0	100.0	94.1
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	77.2	100.0	88.2	100.0	100.0	94.1
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	89.5	91.7	88.2	98.3	100.0	100.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	94.7	100.0	100.0	100.0	100.0	100.0
Pf and Pan								
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	86.0	83.3	88.2	100.0	100.0	100.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	100.0	95.8	100.0	100.0	100.0	100.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	66.7	91.7	88.2	98.3	100.0	100.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	96.5	100.0	100.0	100.0	100.0	100.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	84.2	100.0	94.1	100.0	100.0	100.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	70.2	91.7	76.5	100.0	100.0	94.1
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	57.9	62.5	70.6	98.3	100.0	100.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	56.1	62.5	70.6	94.7	95.8	82.4
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	40.4	37.5	47.1	93.0	100.0	94.1
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	40.4	37.5	41.2	93.0	100.0	94.1
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	66.7	70.8	76.5	98.3	100.0	100.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	91.2	100.0	88.2	100.0	100.0	100.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	93.0	100.0	94.1	98.3	100.0	100.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	73.7	87.5	88.2	100.0	100.0	100.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	98.3	100.0	100.0	100.0	100.0	100.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	70.2	87.5	82.4	100.0	100.0	100.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	91.2	95.8	94.1	100.0	100.0	100.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	84.2	100.0	88.2	98.3	100.0	100.0
Pf and Pv								
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	84.2	100.0	94.1	100.0	100.0	100.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	98.3	100.0	100.0	100.0	100.0	100.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	91.2	100.0	100.0	100.0	100.0	100.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	84.2	100.0	94.1	100.0	100.0	100.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	87.7	100.0	100.0	100.0	100.0	100.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	75.4	95.8	94.1	96.5	100.0	100.0

Table A4.4 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µl Panel detection score[a] by continent of sample origin			2000[b] parasites/µl Panel detection score[a] by continent of sample origin		
			Africa (n=57)	Asia (n=24)	South America (n=17)	Africa (n=57)	Asia (n=24)	South America (n=17)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	56.1	66.7	82.4	100.0	100.0	100.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	84.2	100.0	94.1	100.0	100.0	100.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	98.3	100.0	100.0	100.0	100.0	100.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	71.9	75.0	82.4	96.5	100.0	100.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	93.0	100.0	100.0	96.5	100.0	100.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	84.2	100.0	94.1	100.0	100.0	100.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	98.3	100.0	100.0	100.0	100.0	100.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	94.7	100.0	100.0	100.0	100.0	100.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	86.0	95.8	88.2	100.0	100.0	100.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	56.1	70.8	70.6	98.3	100.0	94.1
Pan only								
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	56.1	70.8	64.7	98.3	100.0	100.0

Africa - United Republic of Tanzania, Central African Republic, Madagascar, Nigeria, Kenya, Ethiopia

Asia - Myanmar, The Philippines, Cambodia

South America - Peru, Colombia

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

[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] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl

[c] PDS presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH).

Table A4.5: ***P. falciparum*** **test line false-positive rates for Phase 2** ***P. vivax*** **samples at low (200) and high (2000) parasite densities (parasites/µl)**

Product	Catalogue number	Manufacturer	*P. vivax* samples (n=34)					
			200 parasites/µl False-positive Pf infection[b] (%)			2000[a] parasites/µl False-positive Pf infection[b] (%)		
			Lot 1 (n=68)	Lot 2 (n=68)	Overall (n=136)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)
Pf only								
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	94.1	100.0	97.1	91.2	100.0	95.6
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	1.5	0.0	0.7	2.9	0.0	1.5
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	4.4	0.0	2.2	14.7	14.7	14.7
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	2.9	0.0	1.5	0.0	0.0	0.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	2.9	0.0	1.5
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	4.5 (67)	4.4	4.4 (135)	2.9	2.9	2.9
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan								
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	4.4	5.9	5.2	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	45.6	22.1	33.8	55.9	29.4	42.7
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	2.9	1.5	2.2	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	1.5	1.5	1.5	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	98.5	99.3	100.0	97.1	98.5
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	1.5	0.0	0.7	2.9	0.0	1.5
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	4.4	0.0	2.2	11.8	0.0	5.9
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	1.5	0.7	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0 (67)	0.0 (135)	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	2.9	1.5	2.2	2.9	0.0	1.5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	2.9	0.0	1.5
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	2.9	0.0	1.5
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	2.9	1.5
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	6.1 (33)	3.0 (67)
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	41.2	19.1	30.2	47.1	52.9	50.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0 (62)	0.0 (130)	0.0	0.0 (33)	0.0 (67)
Pf and Pv								
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.0	0.0	2.9	0.0	1.5
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	1.5	0.0	0.7	5.9	0.0	2.9
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	4.4	1.5	2.9	5.9	0.0	2.9
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.5 *(continued)*

Product	Catalogue number	Manufacturer	*P. vivax* samples (n=34)					
			200 parasites/µl False-positive Pf infection[b] (%)			2000[a] parasites/µl False-positive Pf infection[b] (%)		
			Lot 1 (n=68)	Lot 2 (n=68)	Overall (n=136)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	1.5	0.0	0.7	2.9	0.0	1.5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	1.5	0.7	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0.0	0.0 (67)	0.0 (135)	2.9	0.0	1.5
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.0	0.0	2.9	0.0	1.5
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	1.5	0.0	0.7	5.9	0.0	2.9
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	2.9	2.9	2.9	2.9	0.0	1.5
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.0	0.0	2.9	0.0	1.5
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	1.5	0.0	0.7	5.9	0.0	2.9
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	1.5	0.0	0.7	2.9	0.0	1.5
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	26.9 (67)	27.9	27.4 (135)	18.2 (33)	20.6	19.4 (67)
Pan only								
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] 1 (3%) of the 34 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[b] Pf line positive indicates a false-positive *P. falciparum* infection

[c] Results presented in the table are based on band intensity of a pf-HRP2 line

[d] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.6: Pan (or Pv) test line false-positive rate for non-Pf infection on Phase 2 *P. falciparum* samples at low (200) and high (2000) parasite densities (parasites/µl)

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=98)					
			200 parasites/µl False-positive non-Pf infection (%)			2000[a] parasites/µl False-positive non-Pf infection (%)		
			Lot 1 (n=196)	Lot 2 (n=196)	Overall (n=392)	Lot 1 (n=98)	Lot 2 (n=98)	Overall (n=196)
Pf only								
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA
Pf and Pan								
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	0.0	0.0 (194)	0.0 (390)	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0 (195)	0.5	0.3 (391)	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.5	0.0	0.3	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	0.0	1.0	0.5	0.0 (97)	0.0	0.0 (195)
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.5	0.3	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0 (195)	0.0 (391)	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0 (195)	0.0 (391)	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	1.0	0.5	0.8	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.5	1.0	0.8	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.5	0.3	1.0	0.0	0.5
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0 (195)	0.0	0.0 (391)	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	2.0	0.0 (189)	1.0 (385)	0.0	0.0 (97)	0.0 (195)
Pf and Pv								
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.5	0.3	1.0	1.0	1.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.5	0.0	0.3	1.0	0.0	0.5
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	1.5	0.0	0.8	0.0	0.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0 (195)	0.5	0.3 (391)	0.0	1.0	0.5
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	1.0	0.5
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	1.0	0.0	0.5	0.0	1.0	0.5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	1.5	0.8	1.0	0.0	0.5

Table A4.6 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=98)					
			200 parasites/µl False-positive non-Pf infection (%)			2000[a] parasites/µl False-positive non-Pf infection (%)		
			Lot 1 (n=196)	Lot 2 (n=196)	Overall (n=392)	Lot 1 (n=98)	Lot 2 (n=98)	Overall (n=196)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	1.0	0.0	0.5	1.0 (97)	5.1	3.1 (195)
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.5	0.3	1.0	1.0	1.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.5	0.0	0.3	1.0	0.0	0.5
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	2.0	1.0	1.5	2.0	2.0	2.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.5	0.3	1.0	1.0	1.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.5	0.0	0.3	1.0	0.0	0.5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	0.5	0.0	0.3	1.0	0.0	0.5
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	8.7	17.9	13.3	11.3 (97)	20.6 (97)	16.0 (194)
Pan only								
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] 5 (5%) of the 98 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl

Table A4.7: Phase 2 false-positive rate for *P. falciparum* test line results on all malaria-negative samples

Product	Catalogue number	Manufacturer	Percentage of false-positive Pf test lines on "clean[a]" negative samples			Percentage of false-positive Pf test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive Pf test lines on samples containing immunological factors[c]		
			Lot 1 (n=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)	Lot 1 (n=50)	Lot 2 (n=50)	Overall (n=100)
Pf only											
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.9	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	98.3	100.0 (115)	99.1 (231)	79.4	94.1	86.8	94.0	100.0	97.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	2.6 (115)	1.7	2.2 (231)	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	6.0	6.0	6.0	11.8	11.8	11.8	18.0	20.0	19.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	8.2 (49)	10.0	9.1 (99)
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1.7	0.9	1.3	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	1.7	0.9	1.3	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	1.7	0.0	0.9	0.0	0.0	0.0	2.0	0.0	1.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	5.2 (115)	5.2 (115)	5.2 (230)	0.0	3.0 (33)	1.5 (67)	6.0	10.0	8.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.9	0.0 (115)	0.4 (231)	5.9	2.9	4.4	2.0	0.0	1.0
Pf and Pan											
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.9	0.4	0.0	0.0	0.0	8.0	12.0	10.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	0.0	0.9 (115)	0.4 (231)	0.0	0.0	0.0	2.0	6.0	4.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[e]	MFV-124F	AZOG, INC.	0.9	1.7 (115)	1.3 (231)	0.0	0.0	0.0	10.0	10.0	10.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	37.1	27.2 (114)	32.2 (230)	29.4	32.4	30.9	22.0	8.0	15.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	2.6 (115)	4.3	3.5 (231)	0.0	11.8	5.9	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	2.6	2.6	2.6	0.0	0.0	0.0	2.0	0.0	1.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	96.6	99.1	97.8	97.1	100.0	98.5	96.0	100.0	98.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	0.9	0.0	0.4	0.0	0.0	0.0	4.0	4.0	4.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	2.6	0.0	1.3	0.0	0.0	0.0	0.0	2.0	1.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	4.0	4.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	2.0	3.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	2.6	0.0	1.3	0.0	0.0	0.0	6.0	10.0	8.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	1.7	0.0	0.9	0.0	0.0	0.0	0.0	2.0	1.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	2.0	0.0	1.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	4.0	4.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	8.0	8.0	8.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	12.0	12.0	12.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	25.9	27.6	26.7	29.4	26.5	27.9	14.3 (49)	4.0	9.1 (99)
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	1.7	0.9 (110)	1.3 (226)	0.0	0.0 (31)	0.0 (65)	2.0	4.0	3.0
Pf and Pv											
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	2.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	1.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	9.5	5.2	7.3	5.9	5.9	5.9	2.0	0.0	1.0

Table A4.7 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive Pf test lines on "clean[a]" negative samples			Percentage of false-positive Pf test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive Pf test lines on samples containing immunological factors[c]		
			Lot 1 (n=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)	Lot 1 (n=50)	Lot 2 (n=50)	Overall (n=100)
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.9	0.4	0.0	0.0	0.0	2.0	6.0	4.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	0.0	2.6	1.3	0.0	0.0	0.0	6.0	8.0	7.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.9	0.9	0.9	0.0	0.0	0.0	2.0	4.0	3.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0.0 (114)	0.0	0.0 (230)	0.0	0.0	0.0	4.0	4.0	4.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	2.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	1.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1.7	0.9	1.3	0.0	0.0	0.0	4.0	4.0	4.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	2.6	1.3	0.0	0.0	0.0	4.0	4.0	4.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	2.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	1.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	5.2	3.5	4.3	2.9	2.9	2.9	2.0	0.0	1.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	2.6	1.7	2.2	2.9	0.0	1.5	4.0	4.0	4.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[e]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	33.9 (115)	30.2	32.0 (231)	5.9	11.8	8.8	26.0	22.0	24.0
Pan only											
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	2.6	1.7	2.2	0.0	0.0	0.0	2.0 (49)	8.0	5.1 (99)

NA, not applicable

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

[a] Blood samples from healthy volunteers with no known current illness or blood abnormality

[b] See Table A4.8 for details

[c] See Table A4.9 for details

[d] Results presented in the table are based on band intensity of a pf-HRP2 line

[e] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.8: Phase 2 false-positive rate for *P. falciparum* in samples containing specific non-malarial infectious pathogens

Product	Catalogue number	Manufacturer	Percentage of false-positive for *Plasmodium* spp. by infectious pathogen							
			Dengue		Schistosomiasis		Leishmaniasis		Chagas	
			Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Pf only										
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	75.0	100.0	91.7	100.0	70.0	90.0	75.0	75.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	12.5	25.0	25.0	16.7	0.0	0.0	0.0	0.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	0.0	12.5	0.0	0.0 (11)	0.0	0.0	0.0	0.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	12.5	0.0	8.3	8.3	0.0	0.0	0.0	0.0
Pf and Pan										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[a]	MFV-124F	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	12.5	16.7	8.3	60.0	60.0	50.0	75.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	8.3	0.0	30.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	87.5	100.0	100.0	100.0	100.0	100.0	100.0	100.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	12.5	12.5	0.0	8.3	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	25.0	25.0	8.3	8.3	10.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	8.3	16.7	0.0	0.0	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	25.0	25.0	8.3	50.0	40.0	50.0	50.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0 (7)	0.0	0.0 (11)	0.0	0.0	0.0	0.0 (3)
Pf and Pv										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	10.0	20.0	25.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.8 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive for *Plasmodium* spp. by infectious pathogen							
			Dengue		Schistosomiasis		Leishmaniasis		Chagas	
			Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	25.0	12.5	0.0	0.0	20.0	10.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	0.0	0.0	0.0	10.0	10.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[a]	05FK100	Standard Diagnostics Inc.	12.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	25.0	50.0	8.3	8.3	0.0	10.0	0.0	0.0
Pan only										
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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

[a] Results presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH)

Table A4.9: Phase 2 false-positive rate for *P. falciparum* in samples containing potentially cross-reacting blood immunological factors

Product	Catalogue number	Manufacturer	Percentage of false-positive for *Plasmodium* spp. by blood immunological factor							
			Rheumatoid factor		Anti-nuclear antibodies		Anti-mouse antibodies		Rapid plasma reagin (RPR) positive	
			Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=26)	Lot 2 (n=26)	Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=10)	Lot 2 (n=10)
Pf only										
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	100.0	100.0	92.3	100.0	100.0	100.0	90.0	100.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	37.5	50.0	11.5	15.4	33.3	33.3	10.0	0.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	25.0	37.5	0.0 (25)	0.0	33.3	33.3	0.0	0.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	10.0	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	25.0	37.5	3.9	0.0	0.0	33.3	0.0	0.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	3.9	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	25.0	25.0	0.0	7.7	50.0	33.3	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[a]	MFV-124F	AZOG, INC.	25.0	37.5	0.0	0.0	50.0	50.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	12.5	12.5	15.4	3.9	66.7	16.7	20.0	10.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	0.0	3.9	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	100.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	50.0	50.0	7.7	7.7	33.3	33.3	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	16.7	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	12.5	0.0	3.9	11.5	33.3	33.3	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	25.0	37.5	0.0	0.0	16.7	33.3	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	25.0	25.0	0.0	3.9	33.3	33.3	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	12.5	0.0	0.0	0.0	16.7	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	25.0	25.0	11.5	15.4	100.0	100.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	25.0	25.0	0.0	3.9	33.3	33.3	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	25.0	25.0	0.0	3.9	66.7	66.7	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.0	16.0 (25)	0.0	16.7	33.3	20.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	16.7	33.3	0.0	0.0
Pf and Pv										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.0	7.7	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.0	12.5	0.0	0.0	0.0	0.0	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	0.0	0.0	3.9	0.0	16.7	0.0	0.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.0	3.9	11.5	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	12.5	0.0	0.0	3.9	66.7	66.7	0.0	0.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	10.0

Table A4.9 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive for *Plasmodium* spp. by blood immunological factor							
			Rheumatoid factor		Anti-nuclear antibodies		Anti-mouse antibodies		Rapid plasma reagin (RPR) positive	
			Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=26)	Lot 2 (n=26)	Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=10)	Lot 2 (n=10)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.0	7.7	0.0	0.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.0	12.5	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	25.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	25.0	25.0	7.7	7.7	66.7	66.7	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.0	7.7	0.0	0.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.0	12.5	0.0	0.0	0.0	0.0	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	0.0	3.9	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[a]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	62.5	62.5	23.1	11.5	50.0	66.7	0.0	0.0
Pan only										
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	0.0	25.0	0.0 (25)	0.0	16.7	33.3	0.0	0.0

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

[a] Results presented in the table is based on a positive pf test line (either pf-HRP2 or pf-pLDH)

Table A4.10: Phase 2 false-positive rate of pan test line results on all malaria-negative samples

Product	Catalogue number	Manufacturer	Percentage of false-positive pan test lines on "clean[a]" negative samples			Percentage of false-positive pan test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive pan test lines on samples containing immunological factors[c]		
			Lot 1 (n=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)	Lot 1 (n=50)	Lot 2 (n=50)	Overall (n=100)
Pf only											
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan											
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	6.0	4.0	5.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	0.0	0.0 (115)	0.0 (231)	0.0	0.0	0.0	4.0	6.0	5.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	0.0 (114)	0.0 (230)	0.0	0.0	0.0	4.0	0.0	2.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0 (115)	0.9	0.4 (231)	0.0	0.0	0.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	88.8	88.8	88.8	94.1	85.3	89.7	94.0	96.0	95.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	3.5	0.9	2.2	2.9	5.9	4.4	16.0	16.0	16.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	1.7	0.0	0.9	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	4.3	2.6	3.5	0.0	0.0	0.0	8.0	8.0	8.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	4.0	4.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	4.0	4.0	4.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	8.0	8.0	8.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	2.0	0.0	1.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	7.8	7.8	7.8	11.8	8.8	10.3	22.0	24.0	23.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	6.0	10.0	8.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.9	1.7	1.3	2.9	5.9	4.4	8.0	10.0	9.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	2.6	0.0	1.3	0.0	0.0	0.0	0.0 (49)	0.0	0.0 (99)
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.9 (110)	0.4 (226)	0.0	0.0 (31)	0.0 (65)	0.0	0.0	0.0
Pf and Pv											
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.9	0.4	0.0	0.0	0.0	2.0	0.0	1.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	3.4	0.0	1.7	0.0	0.0	0.0	2.0	0.0	1.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	0.0	0.9	0.4	0.0	0.0	0.0	10.0	10.0	10.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	1.7	0.9	1.3	0.0	0.0	0.0	4.0	4.0	4.0

Table A4.10 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive pan test lines on "clean[a]" negative samples			Percentage of false-positive pan test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive pan test lines on samples containing immunological factors[c]		
			Lot 1 (n=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=34)	Lot 2 (n=34)	Overall (n=68)	Lot 1 (n=50)	Lot 2 (n=50)	Overall (n=100)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0 (114)	1.7	0.9 (230)	0.0	0.0	0.0	4.0	4.0	4.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.9	0.4	0.0	0.0	0.0	2.0	0.0	1.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	3.4	1.7	2.6	11.8	5.9	8.8	12.0	14.0	13.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.9	0.4	0.0	0.0	0.0	2.0	0.0	1.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	0.9	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	26.1 (115)	45.7	35.9 (231)	8.8	11.8	10.3	10.0	12.0	11.0
Pan only											
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	2.6	1.7	2.2	0.0	0.0	0.0	2.0 (49)	8.0	5.1 (99)

NA, not applicable

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

[a] Blood samples from healthy volunteers with no known current illness or blood abnormality

[b] See Table A4.8 for details

[c] See Table A4.9 for details

[d] Pan test line

[e] *P. vivax* test line

Table A4.11: Heat stability testing results for *P. falciparum* (or pan[a]) test line on a *P. falciparum* samples at low parasite density (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C[b]

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf only																										
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	15.0	0.0	1.1	15.0	0.0	1.0	0.0	0.0	0.0	14.0	0.0	1.0	3.0	0.0	1.0	14.0	0.0	1.0	2.0	0.0	1.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	15.0	0.0	2.1	15.0	0.0	3.0	15.0	0.0	3.0	15.0	0.0	3.0	15.0	0.0	3.0	15.0	0.0	3.0	15.0	0.0	2.7	15.0	0.0	3.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.2	15.0	0.0	3.0	15.0	0.0	2.1	15.0	0.0	2.8	15.0	0.0	3.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.2	15.0	0.0	1.0	11.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.7	15.0	0.0	1.5	15.0	0.0	1.9	15.0	0.0	1.7	15.0	0.0	2.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	15.0	0.0	2.1	15.0	0.0	2.3	15.0	0.0	3.0	15.0	0.0	2.1	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.9
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	15.0	0.0	2.8	15.0	0.0	3.9	15.0	0.0	3.0	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	3.0	15.0	0.0	2.7
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	15.0	0.0	2.1	15.0	0.0	1.9	15.0	0.0	1.9	14.0	0.0	1.6	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.8
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.9	7.0	0.0	1.0	10.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	2.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	15.0	0.0	1.8	15.0	0.0	2.0	15.0	0.0	1.6	14.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1
Pf and Pan																										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	1.5	15.0	0.0	2.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	14.0	0.0	0.9	15.0	0.0	1.0	15.0	0.0	1.2	14.0	0.0	1.1	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	0.0	0.0	0.0	4.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0	7.0	0.0	1.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	2.3	15.0	0.0	2.7	15.0	0.0	2.9	15.0	0.0	2.7	15.0	0.0	2.7
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	15.0	0.0	1.7	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.1	15.0	0.0	2.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	14.0	1.0	2.0	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.2	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	3.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	15.0	0.0	1.7	14.0	0.0	1.8	15.0	0.0	2.0	14.0	0.0	1.6	15.0	0.0	1.9	13.0	0.0	1.5	15.0	0.0	2.0	15.0	0.0	1.5
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	15.0	0.0	2.1	15.0	0.0	2.7	15.0	0.0	2.7	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	2.2	15.0	0.0	3.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	3.0	0.0	1.0	14.0	0.0	1.0	6.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	8.0	0.0	1.0	15.0	0.0	1.0	12.0	0.0	1.1
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	15.0	0.0	1.0	15.0	0.0	1.6	14.0	0.0	1.0	15.0	0.0	1.3	15.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	15.0	0.0	2.0	15.0	0.0	1.5	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	1.5	15.0	0.0	2.0	15.0	0.0	1.6	15.0	0.0	2.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	15.0	0.0	1.6	15.0	0.0	1.0	15.0	0.0	1.1	14.0	0.0	1.0	15.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	1.1	15.0	0.0	1.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	15.0	0.0	3.0	15.0	0.0	2.9	15.0	0.0	2.2	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.5	15.0	0.0	2.2	15.0	0.0	2.1
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	13.0	0.0	1.0	15.0	0.0	2.0	15.0	0.0	1.0
ParaHIT - Total (Dipstick)	55IC201-10	Span Diagnostics Ltd.	15.0	0.0	2.0	15.0	0.0	1.5	15.0	0.0	2.0	13.0	0.0	1.5	7.0	5.0	1.1	7.0	4.0	1.7	15.0	0.0	2.0	15.0	0.0	2.0

Table A4.11 *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
ParaHIT - Total (Device)	55IC202-10	Span Diagnostics Ltd.	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	2.3	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	2.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	15.0	0.0	2.9	14.0	1.0	2.0	14.0	1.0	2.3	15.0	0.0	2.5	15.0	0.0	2.1	15.0	0.0	2.8	15.0	0.0	2.7	15.0	0.0	3.0
Pf and Pv																										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	15.0	0.0	2.8	15.0	0.0	2.4	15.0	0.0	3.0	15.0	0.0	2.5	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	15.0	0.0	2.7	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	2.8	15.0	0.0	1.9
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	15.0	0.0	2.2	15.0	0.0	2.1	15.0	0.0	3.0	15.0	0.0	2.2	15.0	0.0	2.1	15.0	0.0	2.1	15.0	0.0	2.7	15.0	0.0	2.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.7	15.0	0.0	2.8	15.0	0.0	2.5	15.0	0.0	1.9	15.0	0.0	2.5	15.0	0.0	2.5
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	15.0	0.0	2.9	15.0	0.0	1.9	15.0	0.0	2.3	15.0	0.0	2.4	15.0	0.0	2.7	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.7
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	4.0	0.0	1.0	8.0	0.0	1.0	9.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	12.0	0.0	1.0	15.0	0.0	1.0	13.0	0.0	1.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	15.0	0.0	1.1	15.0	0.0	1.8	15.0	0.0	1.0	15.0	0.0	1.6	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.1
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	15.0	0.0	2.8	15.0	0.0	2.4	15.0	0.0	3.0	15.0	0.0	2.5	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	15.0	0.0	2.7	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	2.8	15.0	0.0	1.9
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	8.0	0.0	1.0	4.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	15.0	0.0	2.0	15.0	0.0	1.4	15.0	0.0	1.0	15.0	0.0	1.0	13.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	2.0	15.0	0.0	1.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	15.0	0.0	2.8	15.0	0.0	2.4	15.0	0.0	3.0	15.0	0.0	2.5	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	15.0	0.0	2.7	15.0	0.0	2.9	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	2.8	15.0	0.0	1.9
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.9	15.0	0.0	2.2	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.8	15.0	0.0	2.8
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	15.0	0.0	2.5	15.0	0.0	2.5	15.0	0.0	2.5	15.0	0.0	3.4	15.0	0.0	2.5	14.0	1.0	2.9	15.0	0.0	2.7	15.0	0.0	3.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	4.0	0.0	1.0	4.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	1.0	1.0	6.0	0.0	1.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	15.0	0.0	1.6	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.6	5.0	0.0	1.0	6.0	0.0	1.0	15.0	0.0	1.1	15.0	0.0	1.9
Pan only																										
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	15.0	0.0	1.0	15.0	0.0	1.5	15.0	0.0	1.6	15.0	0.0	1.3	15.0	0.0	0.9	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0

ND, not determined

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

[a] For pan-only tests

[b] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

[c] Results presented in the table are based on band intensity of a pf-HRP2 line

[d] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.11a: Heat stability testing results for pan test line of combination RDTs on a *P. falciparum* sample at low parasite density (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	0.0	0.0	8.0	0.0	1.0	10.0	0.0	1.0	14.0	0.0	1.0	10.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	8.0	0.0	1.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	15.0	0.0	1.0	8.0	0.0	1.0	15.0	0.0	1.1	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	1.0	0.0	1.0	0.0	0.0	0.0	5.0	0.0	1.0	1.0	0.0	1.0	2.0	0.0	1.0	2.0	0.0	1.0	3.0	0.0	1.7	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	6.0	0.0	1.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0	10.0	0.0	1.0	9.0	0.0	1.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	0.0	5.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	0.0	15.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0	0.0	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	12.0	0.0	1.0	14.0	0.0	1.0	3.0	0.0	1.0	1.0	0.0	1.0	14.0	0.0	1.0	11.0	0.0	1.0	15.0	0.0	1.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0	0.0	5.0	1.0	0.8	0.0	1.0	0.0	3.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	9.0	0.0	1.0	0.0	0.0	0.0
Pf and Pv																										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.11a *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/ PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

Table A4.12: Heat stability testing results for *P. falciparum* (or pan[a]) test line on a *P. falciparum* samples at high parasite density (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf only																										
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	1.4	5.0	0.0	2.2	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	2.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	5.0	0.0	2.8	5.0	0.0	3.2	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	2.0	5.0	0.0	2.6	5.0	0.0	2.6	5.0	0.0	4.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	5.0	0.0	3.4	5.0	0.0	3.6	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	3.2	5.0	0.0	3.8	5.0	0.0	3.0	5.0	0.0	3.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	5.0	0.0	3.4	5.0	0.0	3.2	5.0	0.0	3.8	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	3.6
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	1.6	5.0	0.0	2.0	5.0	0.0	3.0	5.0	0.0	4.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Pf and Pan																										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	5.0	0.0	4.0	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.4	5.0	0.0	4.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.8	5.0	0.0	3.6	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	1.0	0.0	1.0	4.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	3.8	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.2	5.0	0.0	3.6	5.0	0.0	3.0	5.0	0.0	2.8	5.0	0.0	3.6	5.0	0.0	3.6
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	5.0	0.0	2.8	5.0	0.0	3.2	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	2.8	5.0	0.0	3.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	5.0	0.0	2.8	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	3.2	5.0	0.0	2.8	5.0	0.0	2.8	5.0	0.0	3.0	5.0	0.0	3.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	3.0	5.0	0.0	3.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	5.0	0.0	3.0	5.0	0.0	2.8	5.0	0.0	2.6	5.0	0.0	2.2	5.0	0.0	2.6	5.0	0.0	2.0	5.0	0.0	3.0	5.0	0.0	2.8
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.4	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	4.0	1.0	2.3	2.0	2.0	3.5	5.0	0.0	4.0	5.0	0.0	4.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0

Table A4.12 *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	5.0	0.0	4.0	4.0	1.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Pf and Pv																										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	3.0	5.0	0.0	3.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	4.0	0.0	3.8	5.0	0.0	3.2	5.0	0.0	3.6	5.0	0.0	3.2	5.0	0.0	2.8	5.0	0.0	2.8	5.0	0.0	3.0	5.0	0.0	3.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.0	4.0	0.0	0.8	5.0	0.0	2.0	5.0	0.0	1.8
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	5.0	0.0	3.2	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	2.8	5.0	0.0	3.4	5.0	0.0	3.4
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	5.0	0.0	1.6	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	2.0	5.0	0.0	1.4
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.6	5.0	0.0	2.0	5.0	0.0	1.4	5.0	0.0	3.0	5.0	0.0	3.2
Pan only																										
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.4	5.0	0.0	0.8	5.0	0.0	1.0	5.0	0.0	3.0	5.0	0.0	3.4

ND, not determined

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

[a] For pan-only tests

[b] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

[c] Results presented in the table are based on band intensity of a pf-HRP2 line

[d] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.12a: Heat stability testing results for pan test line of combination RDTs on a *P. falciparum* sample at high parasite density (2000 parasites/µl). Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	0.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0	1.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	3.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	2.0	5.0	0.0	1.2	5.0	0.0	1.2	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	1.4
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	5.0	0.0	1.8	5.0	0.0	1.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.4	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	5.0	0.0	1.0	5.0	0.0	1.0	2.0	0.0	1.0	3.0	0.0	1.0	4.0	0.0	1.0	3.0	0.0	1.0	3.0	0.0	1.0	2.0	0.0	1.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	5.0	0.0	1.6	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.4	5.0	0.0	1.6	5.0	0.0	1.2	5.0	0.0	1.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	1.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.0	0.0	0.0	0.0	5.0	0.0	1.0	5.0	0.0	1.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	4.0	0.0	1.0	5.0	0.0	1.0	0.0	0.0	0.0	4.0	0.0	1.0	5.0	0.0	1.0	0.0	0.0	0.0	5.0	0.0	1.0	5.0	0.0	1.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	5.0	0.0	1.0	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	5.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.0	0.0	1.0	0.0	0.0	2.0	0.0	5.0	0.0	1.0	5.0	0.0	1.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	5.0	0.0	1.0	4.0	1.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0
Pf and Pv																										
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.12a *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing						35°C						45°C						4°C					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/ PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

Table A4.13: Heat stability testing results for *P. falciparum* (or pan) test line on parasite negative samples. Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C[b]

Product	Catalogue number	Manufacturer	Baseline testing				35°C				45°C				4°C			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf only																		
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	30301025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f. test	A03-11-322	Artron Laboratories Inc.	3.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	4.0	0.0
Wondfo One Step Malaria P.f Test	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan																		
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[c]	MFV-124F	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[d]	MFV-124F	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	0.0	2.0	0.0	0.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	0.0	0.0	4.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	4.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	4.0	0.0	4.0	0.0	2.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv																		
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.13 *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing				35°C				45°C				4°C			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	3.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	0.0	0.0	0.0	0.0	4.0	0.0	2.0	0.0	4.0	0.0	4.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[c]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[d]	05FK100	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	3.0	0.0	4.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	4.0	0.0	4.0	0.0
Pan only																		
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0

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

[a] For pan-only tests

[b] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

[c] Results presented in the table are based on band intensity of a pf-HRP2 line

[d] Results presented in the table are based on band intensity of a pf-pLDH line

Table A4.13a: Heat stability testing results for pan test line of combination RDTs on parasite negative samples. Positivity rate at baseline, and after 60 days incubation at 4°C, 35°C and 45°C

Product	Catalogue number	Manufacturer	Baseline testing				35°C				45°C				4°C			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf and Pan																		
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	AZOG, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection kit	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
ICT MALARIA COMBO	ML02	ICT INTERNATIONAL	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10	IND Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (Pte.) Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	0.0	0.0	3.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv																		
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ - Rapid test for Malaria Pv/Pf	50300025	Zephyr Biomedicals	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.13a *(continued)*

One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

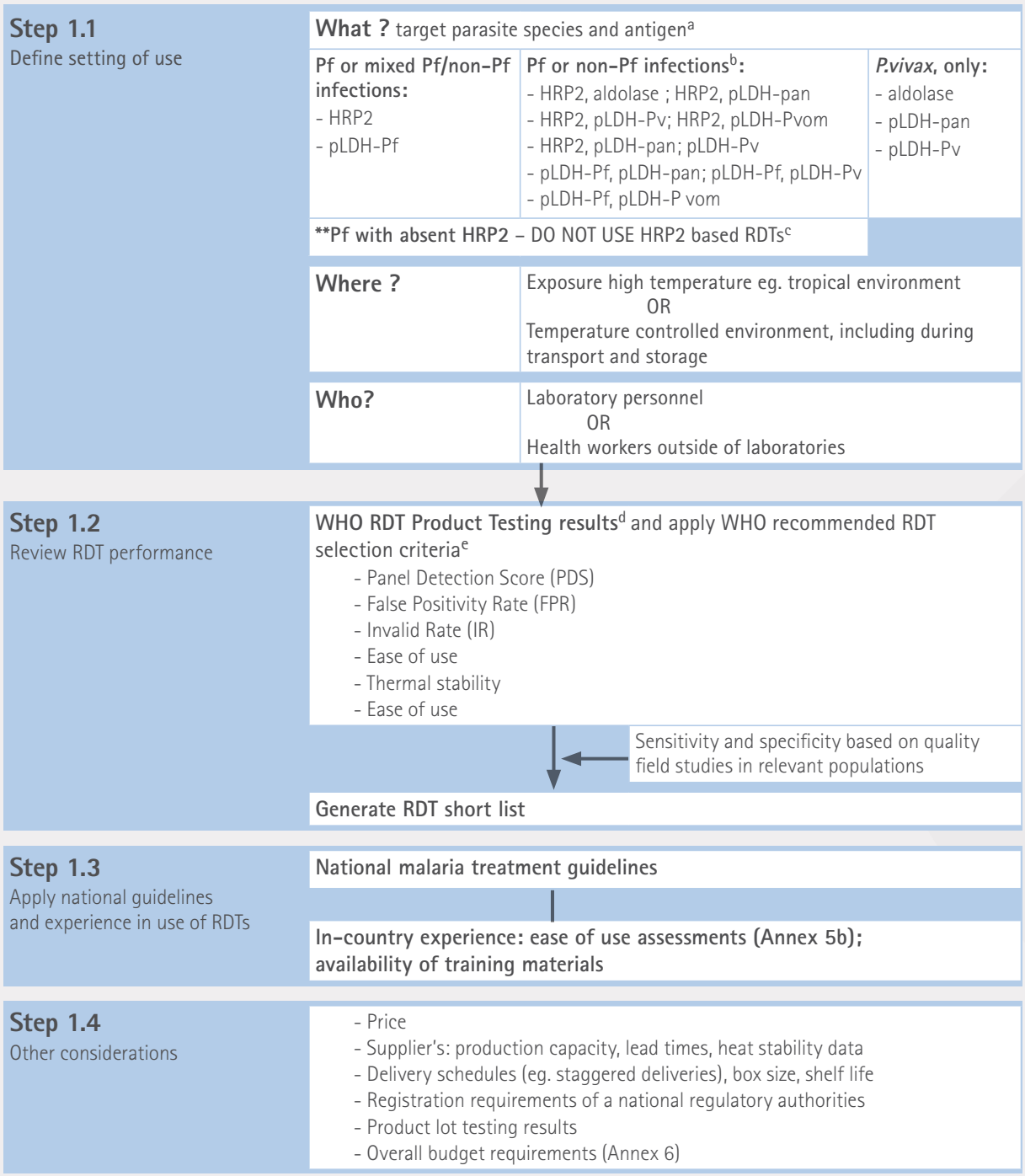
NA, not applicable

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

[a] Positive results presented in the table are based on stability of a positive reader 1 or reader 2 result

Annex 5a: Selection of an appropriate RDT

Figure A5.1 How to select of an appropriate RDT



[a] Pf only or mixed Pf/non Pf infections: Most area of sub-Saharan Africa and lowland Papua New Guinea; : Pf and non-Pf invfections (single species): Most endemic areas of Asia and the Americas and isolated areas of the Horn of Africa; Mainly vivax-only: areas of East Asia, central Asia, South America, and some highland areas elsewhere

[b] Tests with a falciparum-specific line and pan-specific line will not distinguish *P. falciparum*-only infections from mixed falciparum infections. Distinguishing falciparum from mixed falciparum-vivax infections only becomes important if a full course of primaquine is routinely given for infections due to *P. vivax*. This must be weighed against the loss of ability to detect *P. malariae* and *P. ovale* if a test has only *P. falciparum* and *P. vivax*-specific lines. Inclusion of further test lines to detect these (eg. Pf-Pv-pan) increases complexity of test interpretation. A programme should prioritize these various advantages and dis-advantages according to local conditions in the initial stage of making procurement decisions.

[c] *P. falciparum* parasites lacking HRP2 +/- HRP3 genes have been identified in parts of South America (Gamboa D et al. PLoS ONE 5(1):e8091.doi:10.1371/journal.pone.000809)

[d] Malaria Rapid Diagnostic Test Performance: Results of WHO product testing of malaria RDTs: Round 1(2008); Round 2 (2009); Round 3 (2011); Round 4 (2012); FIND Malaria RDT Product Testing: Interactive Guide - *http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp*

[e] WHO RDT procurement criteria : *http://www.who.int/malaria/diagnosis_treatment/diagnosis/en/index.html*

For a comprehensive guide to procurement of malaria RDTs extending beyond selection to quantification, budgeting, technical specifications, management of tenders, contracts, supply management and monitoring of supplier performance and managing product variations, see the "Good Practices for selecting and procuring rapid diagnostic tests for malaria" *(6)*

Annex 5b: Malaria RDT field assessment and RDT anomalies

Obtain samples of each malaria RDT under consideration (at least one box packaged as intended for delivery to end users.)

Obtain malaria parasite-negative blood samples, and where readily accessible, parasite-positive blood samples for testing against RDTs. The purpose of this evaluation, on a limited number of RDTs, is to assess aspects of packaging, safety and ease-of-use, **and not to assess diagnostic accuracy.**

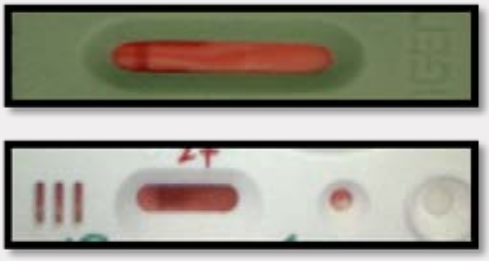
Table A5.1 Field assessment of RDT packaging, safety and ease-of-use to guide product selection

Date of assessment				
Name of RDT				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed packages				
The correct number of RDTs are in the box				
A desiccant is included				
An expiry date is visible on the package				
All required accessories are included (test, buffer, blood transfer device, alcohol swab, lancet, gloves, test tubes (for dipsticks))				If no, what is not included:
Instructions				
Instructions are included				
Instructions are in the national language(s)				
The instructions are for the correct product				
The instructions include diagrams				
The diagrams are accurate (specifically order of test lines and results interpretation)				
Preparation and Procedure				
It is easy to write on the test device				
It is easy to open the test pouch				
The test lines on the device are clearly labelled				
It is easy to use the device for blood collection				
It is easy to open the buffer bottle				
The buffer bottle dispenses even drops				
It is easy to fill the sample well correctly with the provided blood transfer device				
It is easy to fill the buffer well correctly (no overflow)				
The buffer flows well through the test strip				
Result Interpretation				
Control and test lines				
Control line is clear				
Test line(s) are clear				
Good clearance of blood by time of reading				If no, number of tests in the box affected:
Steps and reading time				
Reading time <30 mins				
Two or less timed steps				
Did you get 1 or more invalid tests (no control line) among the last 10 tests you performed?				
If YES, how many?				
Safety				
Are there mixing wells (risk of blood splash)?				
Retractable needle for finger prick?				
Is the RDT strip exposed eg. dipstick test format?				
Do you have any safety problems/concerns regarding the waste disposal? (Please describe)				

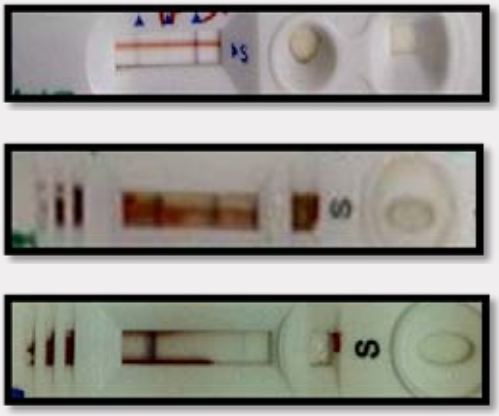
Figure A5.2 Malaria RDT anomalies encountered in production lots

Below are examples of RDT anomalies encountered during WHO Malaria RDT Product Testing at the CDC. Since mid-2012, WHO-FIND Lot Testing laboratories are reporting these anomalies to requesters [1]. In most cases, these anomalies do not invalidate the results, as reactivity in the control and test line areas are still visible, but they may pose challenges to health workers interpreting the results. Furthermore, they should be reported to manufacturers.

A – Red background (residual blood smear that could obscure test and control lines)



B – Incomplete clearing with residual streaking blood

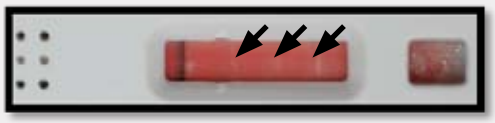


Notes: Poor clearing of blood may obscure weak positive test lines, causing false negative results. Faint background staining is relatively common, and should only be commented on if intensity is significant, similar to the pictures shown. If a test line is visible despite blood streaking, the test result should be reported as 'positive.'

C – Failure to Flow

Blood and buffer did not run the length of the strip

D – Ghost test lines



Note: White lines appear on a blood-stained background. Ghost lines do not indicate a positive test result; positive test lines are those that are darker than the strip's background color.

[1] http://www.finddiagnostics.org/export/sites/default/programs/malaria-afs/docs/lot_testing/Malaria_RDT_functional_anomalies.pdf (accessed 31 October 2012)

E – Patchy or broken test line(s)

F – Faint test line(s)

G – Diffuse test line(s)

Note: Test line appears wider than control line, without clearly defined edge.

Annex 6: Introducing RDT-based malaria diagnosis into national programmes

As parasite-based diagnosis is introduced at smaller clinics and village level for case management, a large number of challenges arise not only in logistical administration but also in managing the health-seeking and health-providing behaviour of patients and health workers. These can be addressed by a clear, time-bound strategic plan that spans planning, implementation, monitoring and evaluation of the diagnostic programme; a process that must commence well before RDTs are procured. Furthermore, funding for the programme must include a significant component for planning and coordination, sensitization/information, education, communication (IEC), training, quality assurance, monitoring and supervision, and logistics, in addition to procurement. Without this, much of the funds expended on RDTs may be wasted, and a loss of confidence in RDT-based diagnosis may hinder the process of strengthening appropriate malaria case management. A focal person, or persons, will be needed to coordinate the overall implementation plan and to ensure that the various agencies that may be involved understand the process and their particular roles.

Examples of wide-scale successful introduction of malaria RDTs are now in existence in various national programmes and comprehensive technical guidance on achieving universal access to malaria diagnostic testing has been published (*30,31*). Figures A6.1 and A6.2 give examples of the steps and timelines for RDT implementation and budget components for a malaria diagnosis programme, respectively. This will need to be modified considerably for each programme.

Key challenges

Changing past thinking that "fever equals malaria unless proven otherwise".

Introducing RDTs will demonstrate that this is not the case. To have an impact on anti-malarial diagnosis and treatment, RDTs must be seen to provide an accurate diagnosis by both health workers and patients alike, that is, they must be as good or better than those relied on previously. A health worker will also need a good alternative to anti-malarial medicines for the management of parasite-negative febrile patients. To achieve and maintain confidence in RDT-based diagnosis, a good quality assurance system must be in place. There must be satisfactory education of health workers, and widespread community sensitization. Knowledge of other causes of fever will be necessary to develop appropriate management algorithms for parasite-negative cases.

Changing and enforcing regulatory requirements

At the national level, regulatory requirements may need to be developed to control the importation and use of malaria RDTs, and new procedures for storage, distribution and inventory management, such as those used for medicines, may need to be developed.

Figure A6.1. Example of malaria RDT implementation steps and timeline[a]

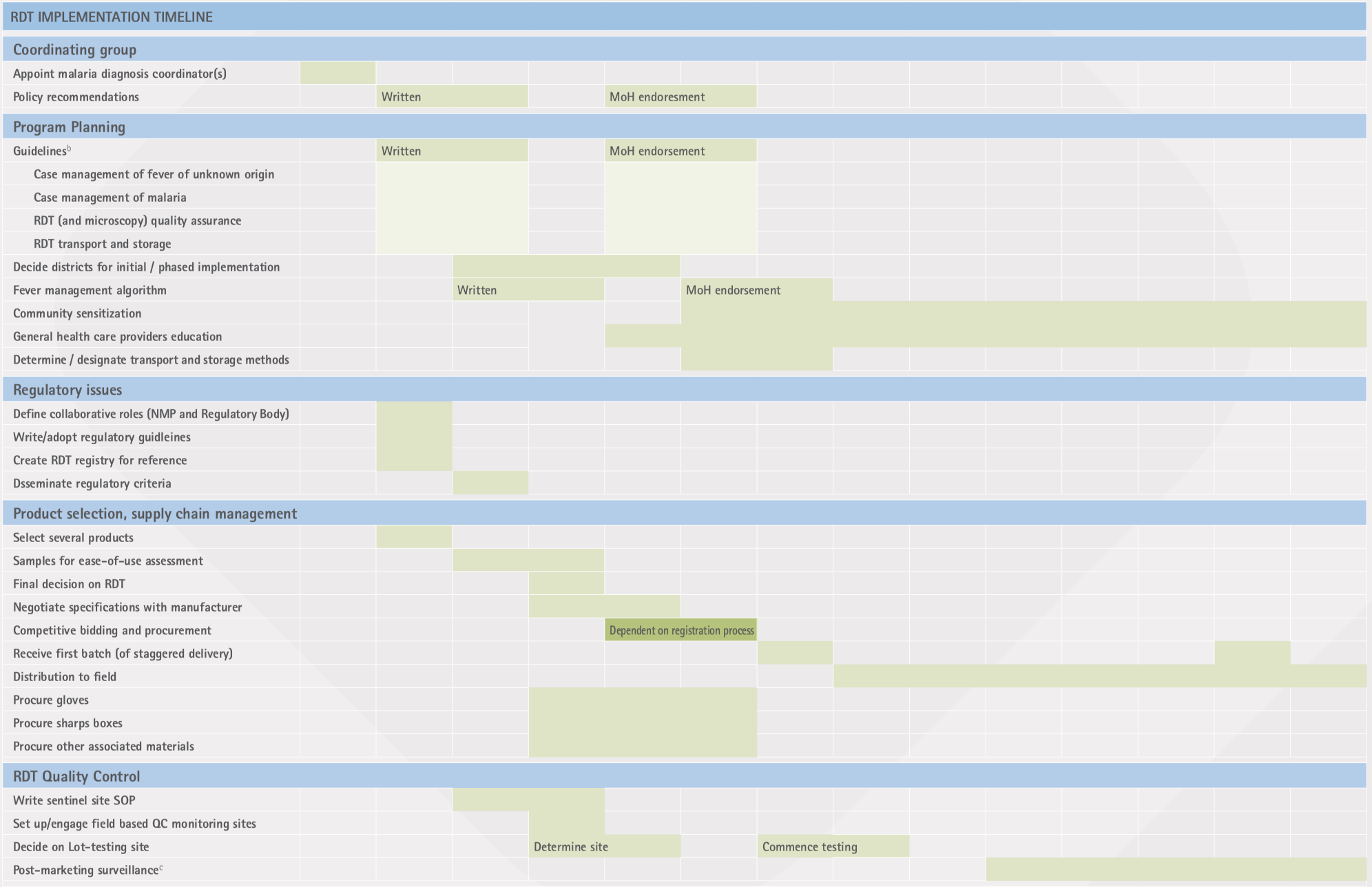
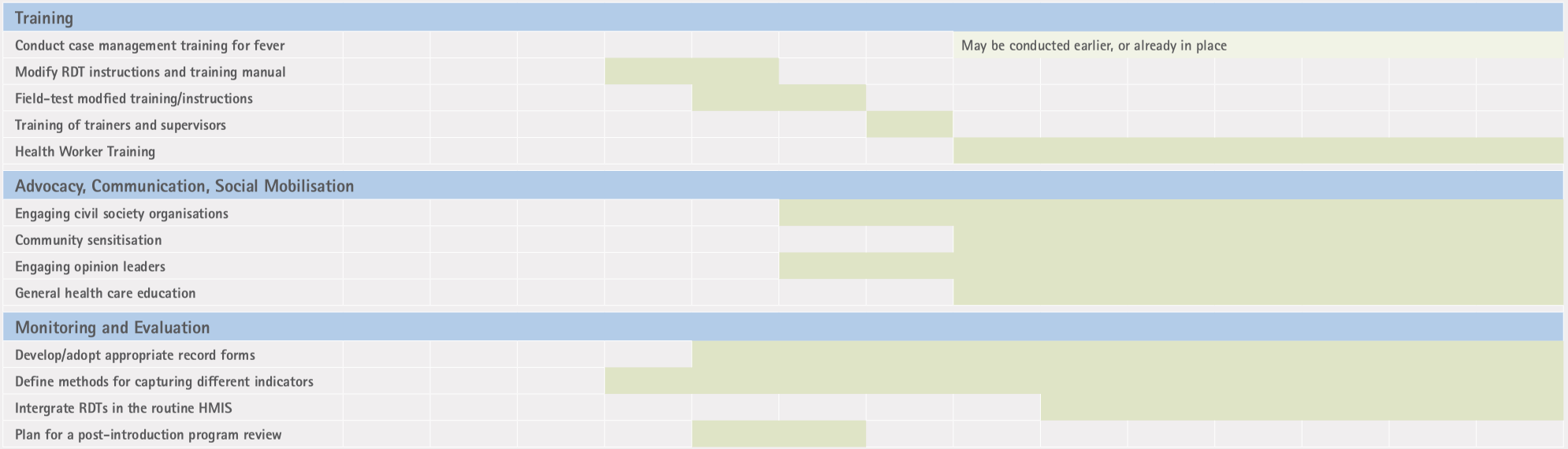


Figure A6.1 *(continued)*



[a] Adapted with permission from FIND and Uganda National Malaria Control Programme
[b] May already be in place
[c] Sentinel site mciroscopy, possibly positive control wells in future

Figure A6.2. Components of the budget for a malaria diagnosis programme[a]

Component	Activities specific to microscopy	Activities specific to RDTs	Activities for management of (malaria and non-malaria) fevers
Preparation of technical guidelines, standard operating procedures and checklists			
Guidelines	Laboratory supervision[b]	RDT transport and storage	Fever management algorithm
Standard operating procedures for diagnostic testing	Microscopy performance	RDT performance	Other tests used at primary care level
Other standard operating procedures	Proficiency testing, validation of routine slide results	RDT storage	
Training material	Training manual for microscopy	Training manual for RDTs	Training manuals for integrated management of fevers
Checklists for supervision	Laboratory visits[b]	Health facility visits	
Procurement and supply of commodities			
Diagnostic tests	Microscopes and related supplies	RDT kits	Urine dipsticks, haemoglobin meter, hematocrit meter, glucometer
Medicines	ACTs		Antibiotics, zinc, inhaled salbutamol, rehydration salts
Other commodities	Gloves, lancets, alcohol, cotton wool, timers, sharps boxes		
Distribution of commodities to the field	All items listed above		
Quality management system			
Pre-shipment testing		Lot-testing	
Training of focal people	Quality management system focal people		
Monitoring the quality management system	Quality monitoring supervision visits and compilation of health information management data		
Training of health workers			
Training of tutors	Expert microscopists	Tutors for RDT performance outside laboratories and clinical management of fever cases	
Training of health workers	Microscopists	Health workers	Clinicians
Training of supervisors	Laboratory supervisors[b]	Clinical supervisors	
Supervision			
Supervisory visits	Laboratory visits[b]	Health facility visits	
Advocacy, communication and social mobilization			
Design of strategies and material	Communication on the need for malaria testing		Communication on other causes of fever
Dissemination of key messages	Through each delivery channel		
Monitoring and evaluation			
Updating the health information management system	Add row for RDTs in laboratory report and column for malaria test results in clinicians' book		Column for other test results in clinicians' book
Train health workers in the new health information management system	Training of person in charge or focal person for reporting on health information management in health facilities		

[a] Adapted with permission (*30*)

[b] To simplify, activities specific to laboratories have been mentioned under 'Microscopy', although both microscopy and RDT are generally performed in laboratories.

NOTES

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