Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: Round 3 (2010-2011)

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FIND foundation for innovative new diagnostics
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Contents

FIGURES

TABLES

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ABBREVIATIONS

ACT	Artemisinin-based combination therapy
AMI	Army Malaria Institute
AusAID	Australian Agency for International Development
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
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*
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 1-3

1.1. Introduction

The World Health Organization estimates that half the world's population are at risk of malaria, with 225 million people developing clinical malaria in 2009 (78% in Africa), and 781,000 deaths (91% in Africa, most being children). Malaria remains endemic in 106 countries, and while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly identified, resulting in over-use of anti-malarial drugs and poor disease monitoring.[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 as they provide parasite-based diagnosis in areas where good quality microscopy cannot be maintained. The number of RDTs available, and the scale of their use, has rapidly increased over the past few years. However, limitations of comparative field trials and the heterogeneous nature of malaria transmission and epidemiology has limited the availability of good quality performance data that national malaria programmes require to make informed decisions on procurement and implementation, and limits the ability to extrapolate results of field trials to different populations and time periods. To this end in 2006, the World Health Organization (WHO), Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched an evaluation programme to assess the comparative performance of commercially available malaria RDTs. This data is guiding procurement decisions and helping to drive improvement in the quality of manufacturing. The results of the first and second rounds of Product Testing were published in 2009 and 2010, and now form the basis of procurement criteria of WHO and UN agencies and national governments.

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

1.2. The WHO Product Testing Programme

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

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

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1 *World Malaria Report 2010.* Geneva, World Health Organization, 2010.

2 *Guidelines for the Treatment of Malaria, Second Edition.* Geneva, World Health Organization, 2010.

3 See full reports of Rounds 1, 2 and 3 for full list of collaborating partners.

4 Working definition of a product can be found here on page 13: *http://www.wpro.who.int/internet/resources.ashx/RDT/docs/pdf_version/web3_QARDTreport.pdf* (accessed 8 September 2011)

1.3. Results of the evaluation

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

The clinical sensitivity of an RDT to detect malaria is highly dependent on the local conditions, including parasite density in the target population. Sensitivity of a test will therefore differ between populations with differing levels of transmission, as their different level of immunity will affect the parasite density at which they exhibit symptoms warranting a diagnostic test. Where transmission rates are low, parasite densities in people with symptoms of malaria are likely to be lower, resulting in tests having a lower sensitivity. For this reason, test performance at 200 parasites/µl is particularly important. The results in this report show comparative performance between RDTs, and give an indication of which products are likely to provide higher sensitivity in the field, particularly in populations with low-density infections. In general, as countries reduce malaria prevalence and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the detection rate at 2000 parasites/µl indicates, the sensitivity of many of these products will be similar in populations with higher parasite densities, although a subset of any population will include vulnerable individuals who may develop illness at low parasite densities (e.g. young children, pregnant women, those well protected by bed nets) and must always be taken into account when interpreting RDT results. An important caveat when predicting field sensitivity from the PDS provided in this report is that the panels used in this evaluation only include parasites known to express the target antigens. While non-expression of the target antigens has not been recorded for aldolase or pLDH, it is known that parasites infecting people in some areas of South America do not express HRP2[7]. 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,[8] and at *www.wpro.who.int/sites/rdt*. An interactive guide to assist in selecting products with performance characteristics most suitable for a particular country health programme is found on the FIND website.[9]

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5 *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

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

7 Gamboa D et al. *PLoS One*, 2010: 5(1): e8091

8 *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

9 Malaria RDT Interactive Guide : *http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing/index.jsp* (accessed 8 Sept.2011)

1.4. Summary of outcomes

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

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

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

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

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

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

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

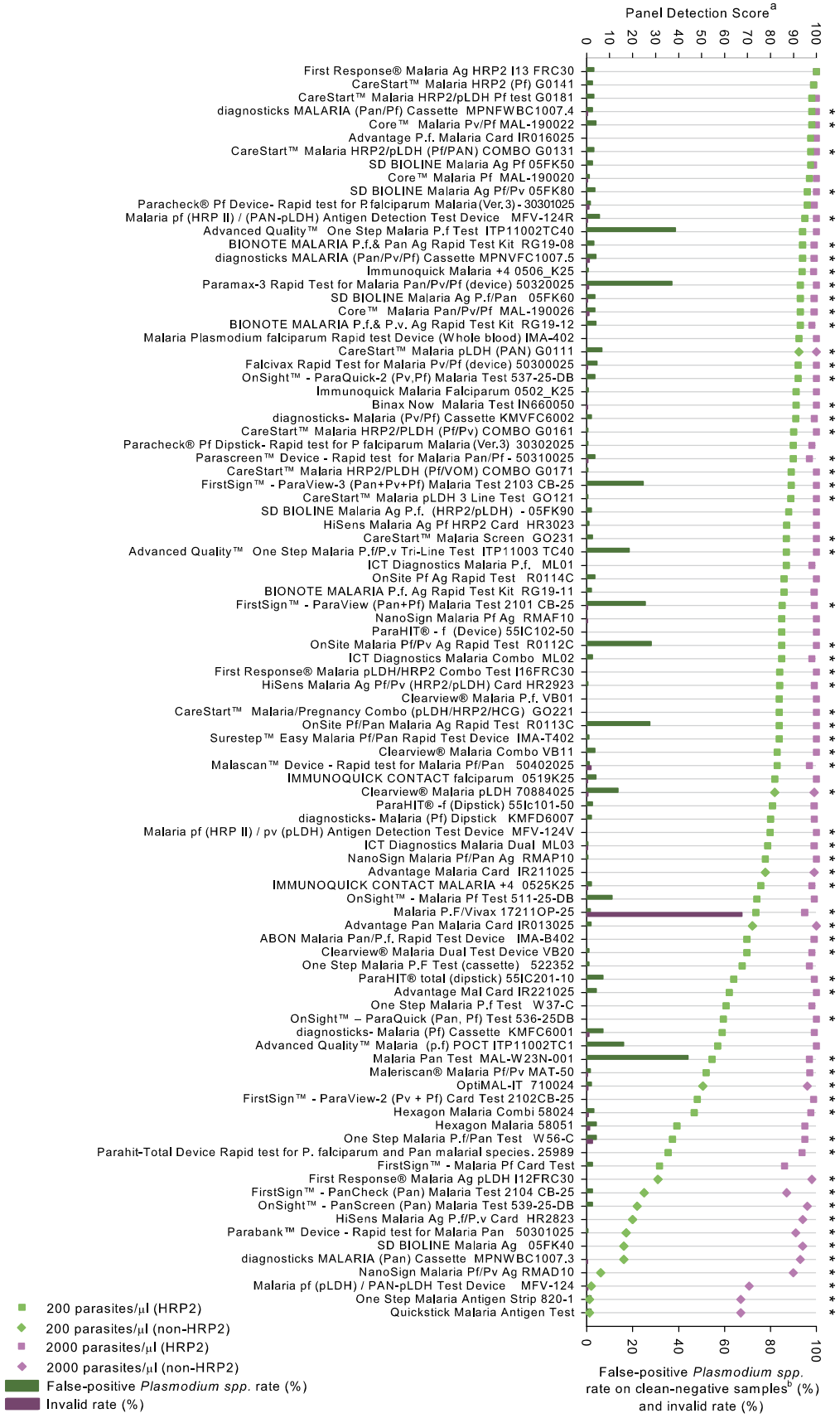
1.5. Use of these results

Accurate diagnosis is vital to good malaria case management, whether based on microscopy or RDTs. The results of this report should be used to short-list RDTs for procurement for use in cases where good microscopy is not available or appropriate. Additionally, it is imperative that procurement decisions based on these results take into consideration local conditions of malaria transmission and illness where the tests will be used (e.g. *Plasmodium* species, target antigen variation, parasite densities, climate), as well as other important considerations, including field-based ease of use assessments, and training/retraining requirements. Furthermore, in order to ensure that the high performance demonstrated by the lots evaluated in the product testing programme is maintained, it is recommended that each lot of RDTs is also tested in a standardized way prior to dispersal to the field.[10] 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'.[11]

[10] The WHO-FIND Malaria RDT Evaluation Programme provides lot-testing capacity in a number of regional laboratories free of charge, and can be accessed through *Malaria_rdt@who.int* and *info@finddiagnostics.org*.

[11] 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 1–3 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000 or 5000) parasite densities (parasites/µl) and clean-negative samples

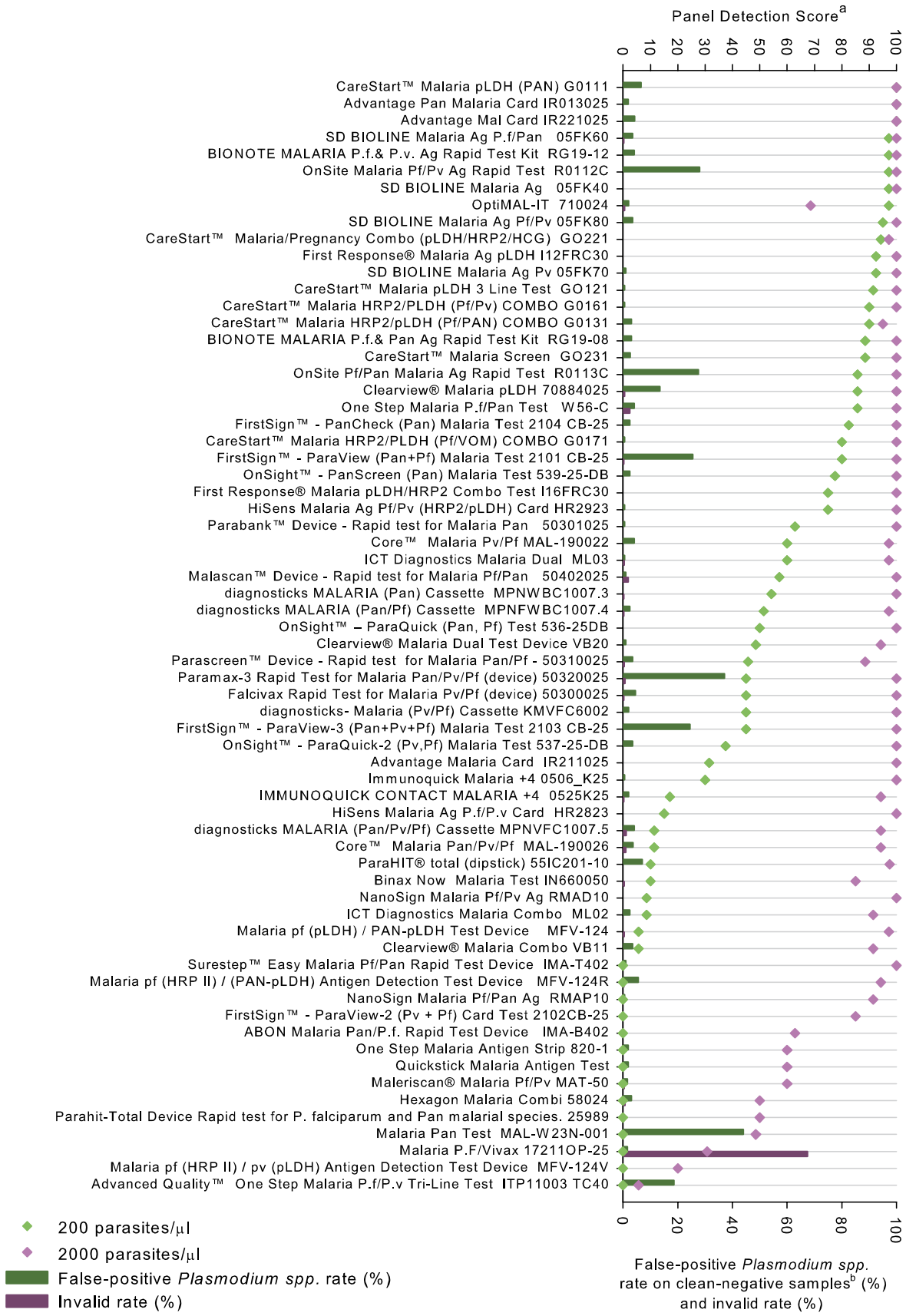


[a] panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.

[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. (see Figure S2)

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



[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.

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

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%) (n=1204)	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													
Advanced Quality™ One Step Malaria P.f Test[j]	ITP11002TC40	InTec Products, Inc.	93.9	N/A	100.0	N/A	N/A	40.0	N/A	35.7	38.5	0.1	3
Advanced Quality™ Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	57.0	N/A	100.0	N/A	N/A	12.5	N/A	17.5	16.1	0.0	1
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	97.5	N/A	100.0	N/A	N/A	1.3	N/A	2.5	0.0	0.0	1
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	85.9	N/A	99.0	N/A	N/A	0.0	N/A	1.4	2.0	0.1	3
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	98.7	N/A	98.7	N/A	N/A	5.0	N/A	7.5	2.4	0.0	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	N/A	100.0	N/A	N/A	0.6	N/A	1.3	3.0	0.0	2
Clearview® Malaria P.f.[j]	VB01	Vision Biotech (Pty) Ltd	83.8	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	N/A	100.0	N/A	N/A	0.0	N/A	0.0	1.0 (198)	0.3	3
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	59.0	N/A	99.0	N/A	N/A	1.9	N/A	2.6 (77)	7.0	0.9	2
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	N/A	99.0	N/A	N/A	2.5	N/A	3.8	2.0	0.0	2
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.	100.0	N/A	100.0	N/A	N/A	0.0	N/A	0.0	3.0	0.0	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	31.7	N/A	86.1	N/A	N/A	12.5	N/A	15.0	2.4 (166)	0.0	1
Hexagon Malaria	58051	Human GmbH	39.2	N/A	94.9	N/A	N/A	7.9 (76)	N/A	2.5	4.2 (167)	1.2	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	87.0	N/A	100.0	N/A	N/A	0.0	N/A	0.0	1.0	0.1	2
ICT Diagnostics Malaria P.f.[j]	ML01	ICT Diagnostics	86.9	N/A	98.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0	3
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	N/A	100.0	N/A	N/A	3.6 (139)	N/A	1.4	4.0 (199)	0.3	3
Immunoquick Malaria Falciparum	0502_K25	Biosynex	91.1	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.6	0.0	1
Malaria *Plasmodium falciparum* Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	92.4	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0	1
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.3	3
One Step Malaria P.F Test (cassette)[j]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	67.7	N/A	97.0	N/A	N/A	0.0	N/A	2.9	1.0	0.2	3
One Step Malaria P.f Test[j]	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	60.6	N/A	98.0	N/A	N/A	0.7 (139)	N/A	0.0	0.0	0.2	3
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	N/A	99.0	N/A	N/A	8.1	N/A	2.5	11.0	0.0	2
OnSite Pf Ag Rapid Test[j]	R0114C	CTK Biotech, Inc.	85.9	N/A	100.0	N/A	N/A	0.7	N/A	0.0	3.5	0.0	3
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3[j]	30301025	Orchid Biomedical Systems	96.0	N/A	99.0	N/A	N/A	0.0 (138)	N/A	1.5 (68)	1.5	0.9	3
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3[j]	30302025	Orchid Biomedical Systems	89.9	N/A	98.0	N/A	N/A	0.0	N/A	1.4	0.5	0.0	3
ParaHIT® - f (Device)[j]	55IC102-50	Span Diagnostics Ltd.	84.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0	3
ParaHIT® -f (Dipstick)[j]	55IC101-50	Span Diagnostics Ltd.	80.8	N/A	99.0	N/A	N/A	0.0	N/A	1.4	2.5	0.0	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[k]	05FK90	Standard Diagnostics Inc.	87.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	2.0	0.0	3
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	97.5	N/A	98.7	N/A	N/A	0.0	N/A	0.0	2.4	0.0	1
Pf and Pan													
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	69.7	0.0	99.0	62.9	0.0	0.0	0.0	0.0	0.0	0.0	3
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	62.0	100.0	100.0	100.0	2.5	0.0	0.0	0.0	4.2	0.0	1
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

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%) (n=1204)	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]		
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
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
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) Malaria Test	2101 CB-25	Unimed International Inc.	85.0	80.0	99.0	100.0	0.0	0.6 (159)	0.5 (199)	0.0	25.5	0.2	2
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
ICT Diagnostics Malaria Combo[j]	ML02	ICT Diagnostics	84.9	8.6	98.0	91.4	0.0	3.6	0.0	5.7	2.5	0.0	3
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	78.8	60.0	99.0	97.1	0.5 (394)	0.0	0.0	1.4	0.5 (199)	0.3	3
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	98.0	94.3	1.8 (395)	5.1 (138)	0.0	0.0	2.0	0.3	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
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 (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
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
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	77.8	0.0	100.0	91.4	0.0	2.9	0.0 (197)	2.9	0.5	0.0	3
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	6.1	8.6	89.9	100.0	0.5	0.0 (139)	0.0	0.0	0.0	0.1	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 Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	83.8	85.7	100.0	100.0	1.3	0.0	0.0	0.0	27.5	0.0	3
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	50.5	97.1	96.0	68.6	1.5	0.0	0.5	20.3 (69)	2.0 (198)	0.5	3
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	64.0	10.0	99.0	97.5	0.0	0.0	0.0	0.0	7.0	0.0	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™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	89.9	45.7	97.0	88.6	1.0 (394)	2.1	0.0 (197)	7.1	3.5 (199)	0.4	3
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.	1.3	0.0	67.1	60.0	2.2	3.8	1.9	0.0	1.8 (167)	0.0	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[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	G0161	Access Bio, Inc.	90.0	90.0	100.0	100.0	0.3	0.6	0.0	0.0	0.5	0.0	2
CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	89.0	80.0	100.0	100.0	1.3	0.0	0.5	0.0	0.5	0.0	2

Table S1 (continued)

Product	Catalogue number	Manufacturer	Panel Detection Score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%) (n=1204)	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]		
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 (device)	50300025	Zephyr Biomedicals	92.0	45.0	100.0	100.0	0.0	1.3	0.0	0.0 (79)	4.5	0.2	2
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	48.1	0.0	98.7	85.0	1.0	3.8	N/A	5.0	0.0 (167)	0.0	1
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
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
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 Malaria Pf/Pv Ag Rapid Test[j]	R0112C	CTK Biotech, Inc.	84.9	97.1	100.0	100.0	5.3	0.0	6.1	0.0	28.0	0.0	3
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
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	N/A	N/A	N/A	N/A	1.8	0.0	1
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	92.4	100.0	100.0	100.0	N/A	N/A	N/A	N/A	6.6	0.0	1
Clearview® Malaria pLDH[j]	70884025	Orgenics Ltd.	81.8	85.7	99.0	100.0	N/A	N/A	N/A	N/A	13.5	0.5	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	N/A	N/A	N/A	N/A	0.0	0.3	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	31.0	92.5	98.0	100.0	N/A	N/A	N/A	N/A	0.0	0.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	25.0	82.5	87.0	100.0	N/A	N/A	N/A	N/A	2.5	0.2	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	22.0	77.5	96.0	100.0	N/A	N/A	N/A	N/A	2.5	0.2	2
Parabank™ Device - Rapid test for Malaria Pan[j]	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	N/A	N/A	N/A	N/A	0.5	0.2	3
Pv only													
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	N/A	92.5	N/A	100.0	0.3	N/A	1.0	N/A	1.0	0.0	2

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

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

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

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

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

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

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

[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). *P. falciparum* PDS based on individual test lines was : pf-pLDH (17.2% at 200p/µl; 97% at 2000p/µl) and pf-HRP2 (87.9% at 200p/µl; 100% at 2000p/µl)

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

Product	Catalogue number	Manufacturer	Percent positive test results for *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															
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	N/A	N/A	N/A	N/A	N/A	N/A	3
Advanced Quality™ Malaria (p.f) POCT	ITP11002TC1	InTec Products, Inc.	80.0	95.0	90.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	95.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	86.7	100.0	90.0	80.0	N/A	N/A	N/A	N/A	N/A	N/A	3
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2
Clearview® Malaria P.f.[a]	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	96.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
diagnosticks- Malaria (Pf) Cassette	KMFC6001	SSA Diagnostics & Biotech Systems	95.0	70.0	55.0	95.0	95.0	95.0	N/A	N/A	N/A	N/A	N/A	N/A	2
diagnosticks- Malaria (Pf) Dipstick	KMFD6007	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2
First Response® Malaria Ag HRP2	I13FRC30	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
FirstSign™ – Malaria Pf Card Test	--	Unimed International, Inc.	20.0	15.0	0.0	100.0	90.0	95.0	N/A	N/A	N/A	N/A	N/A	N/A	1
Hexagon Malaria	58051	Human GmbH	50.0	35.0	60.0	95.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2
ICT Diagnostics Malaria P.f.[a]	ML01	ICT Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
Immunoquick Malaria Falciparum	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
Malaria *Plasmodium falciparum* Rapid test Device (Whole blood)	IMA-402	ACON Laboratories, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	96.7	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
One Step Malaria P.F Test (cassette)[a]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	63.3	0.0	0.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
One Step Malaria P.f Test[a]	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	93.3	90.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	100.0	95.0	90.0	100.0	100.0	65.0	N/A	N/A	N/A	N/A	N/A	N/A	2
OnSite Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3[a]	30301025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3[a]	30302025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
ParaHIT® - f (Device)[a]	55IC102-50	Span Diagnostics Ltd.	100.0	96.7	100.0	100.0	100.0	90.0	N/A	N/A	N/A	N/A	N/A	N/A	3
ParaHIT® -f (Dipstick)[a]	55IC101-50	Span Diagnostics Ltd.	100.0	100.0	56.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	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	N/A	N/A	N/A	N/A	N/A	N/A	3
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	1
Pf and Pan															
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	100.0	80.0	90.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	55.0	95.0	100.0	95.0	55.0	45.0	40.0	100.0	100.0	100.0	1
Binax Now Malaria Test	IN660050	Inverness Medical Innovations, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	5.0	0.0	0.0	95.0	95.0	75.0	1
BIONOTE MALARIA P.f.& 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

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			
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
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
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) Malaria Test	2101 CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	95.0	40.0	40.0	100.0	100.0	100.0	2
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
ICT Diagnostics Malaria Combo[a]	ML02	ICT Diagnostics	100.0	100.0	96.7	100.0	100.0	90.0	0.0	0.0	0.0	90.0	30.0	0.0	3
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	100.0	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	100.0	80.0	0.0	3
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	50.0	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
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 (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
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
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	100.0	100.0	100.0	100.0	100.0	90.0	0.0	0.0	0.0	0.0	0.0	0.0	3
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 Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	3.3	66.7	83.3	100.0	100.0	80.0	3
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	100.0	90.0	0.0	0.0	0.0	0.0	100.0	90.0	0.0	3
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™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	100.0	100.0	3
Quickstick Malaria Antigen Test	--	Innovatek Medical Inc.	15.0	0.0	0.0	65.0	50.0	0.0	15.0	0.0	0.0	65.0	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[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	N/A	N/A	N/A	N/A	N/A	N/A	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	100.0	96.7	96.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	100.0	96.7	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	Access Bio, Inc.	100.0	100.0	95.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2

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			
CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	100.0	95.0	95.0	100.0	100.0	95.0	N/A	N/A	N/A	N/A	N/A	N/A	2
Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	2
FirstSign™ – ParaView-2 (Pv + Pf) Card Test	2102CB-25	Unimed International, Inc.	95.0	70.0	0.0	100.0	95.0	75.0	N/A	N/A	N/A	N/A	N/A	N/A	1
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	100.0	60.0	30.0	100.0	90.0	95.0	N/A	N/A	N/A	N/A	N/A	N/A	2
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	100.0	100.0	100.0	100.0	100.0	85.0	N/A	N/A	N/A	N/A	N/A	N/A	2
OnSite Malaria Pf/Pv Ag Rapid Test[a]	R0112C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	N/A	N/A	N/A	N/A	N/A	N/A	3
SD BIOLINE Malaria Ag Pf/Pv	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	N/A	N/A	N/A	N/A	N/A	N/A	2
Pf, Pv and Pan															
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	100.0	100.0	100.0	100.0	90.0	100.0	0.0	0.0	0.0	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.	N/A	N/A	N/A	N/A	N/A	N/A	50.0	65.0	70.0	100.0	100.0	100.0	1
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	100.0	100.0	90.0	100.0	100.0	100.0	1
Clearview® Malaria pLDH[a]	70884025	Orgenics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	96.7	93.3	100.0	100.0	100.0	100.0	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A	0.0	0.0	0.0	80.0	100.0	80.0	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	50.0	80.0	55.0	100.0	100.0	100.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	N/A	N/A	N/A	N/A	N/A	N/A	25.0	5.0	10.0	100.0	100.0	100.0	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	5.0	35.0	15.0	100.0	100.0	100.0	2
Parabank™ Device - Rapid test for Malaria Pan[a]	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	0.0	0.0	0.0	90.0	100.0	100.0	3
Pv only															
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2

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 on 200p/µl and 2000p/µl samples were, respectively : pf-pLDH (0%; 33.3% detected at baseline and 0% ; 33.3% detected post 60 d incubation at 35°C, 45°C) and pf-HRP2 (100%; 100% at baseline and 100%; 100% post 60 d incubation at 35°C, 45°C)

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

Manufacturer	Initial Testing			Subsequent Testing		
	Round	Product Name	Catalogue No	Round	Product Name	Catalogue No
AZOG, Inc.	1	Malaria Pf (HRPII)/pv-LDH) Antigen Detection Test Device[a]	MFV-124R	3	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R
Blue Cross Bio-Medical (Beijing) Co., Ltd.	2	One Step Malaria Pf Test (cassette)	522352	3	One Step Malaria 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	OnSite Pf/Pan Malaria Ag Rapid Test	R0113C
	2	Onsite Pf/Pv Ag Rapid Test	R0112C	3	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C
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	One Step Malaria P.f Test	W37-C
ICT Diagnostics	1	ICT Malaria Combo Cassette Test	ML02	3	ICT Diagnostics Malaria Combo	ML02
	1	ICT Malaria Pf Cassette Test	ML01	3	ICT Diagnostics Malaria P.f	ML01
InTec Products, Inc.	1	ADVANCED QUALITY™ One Step Malaria (p.f.) Test (whole blood)	ITP11002TC40	3	Advanced Quality™ One Step Malaria P.f Test	ITP11002 TC40
Orchid Biomedical Systems	1	Paracheck Pf Rapid test for P.falciparum Malaria (Device)	30301025	3	Paracheck® Pf Device - Rapid test for *P. falciparum* Malaria (Ver. 3)	30301025
	1	Paracheck Pf Rapid test for P.falciparum Malaria (Dipstick)	30302025	3	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. (now Alere Healthcare (Pty) Ltd)	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
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	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025

[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 Code. 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 changes/product codes. Manufacturer confirmed compliance with product definition.

2. WHO MALARIA RDT PRODUCT TESTING: ROUND 3 EXECUTIVE SUMMARY

2.1. Introduction

The World Health Organization estimates that half the world's population are at risk of malaria, with 225 million people developing clinical malaria in 2009 (78% in Africa), and 781,000 deaths (91% in Africa, most being children). Malaria remains endemic in 106 countries, , and while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly identified, resulting in over-use of anti-malarial drugs and poor disease monitoring (*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, 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), Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched an evaluation programme to assess the comparative performance of commercially available malaria RDTs. This data is guiding procurement decisions and driving improvement in the quality of manufacturing. The results of the first round of Product Testing were published in April 2009, and presently form the basis of procurement criteria of WHO, other UN agencies and national governments (*3*).

This Report provides data on Round 3 of Product Testing, performed at the United States Centers for Disease Control and Prevention, Division of Malaria and Parasitic Diseases (CDC) in 2010-2011. It provides performance data on 50 products. This evaluation should be seen as additive to the Round 1 and Round 2 evaluations published in 2009 and 2010 respectively (*3,4*). The three 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 or 3, the most recent result replace those reported previously. The evaluation panels were essentially equivalent, and the same testing protocols were 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 50 products from 23 manufacturers[12] 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 fourth round of product testing began in June 2011, and results will be published in 2012.

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

[12] Since their application for Round 3, several companies have been acquired by Alere™ (Table 1).

many settings (5), 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, more so than in previous rounds. Re-submitted products (23 of 50 evaluated) generally maintained high levels of performance seen in earlier rounds or substantially increased their PDS. High false-positive rates are seen for several products against the blood samples containing specific immunological abnormalities (eg. 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.

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 between 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 is 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 of transport and storage have demonstrated great 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 Round 1 (2008) and Round 2 (2009), with the results of re-submitted products replacing those reported in earlier rounds (*3,4*). 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' (*6*).

3. BACKGROUND

In 2010, WHO estimated that 3.3 billion persons were at risk of acquiring malaria. Of these, 225 million people were infected in 2009 (78% in Africa), and 781,000 died (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, in combination with increased coverage of malaria control programs, are likely 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.

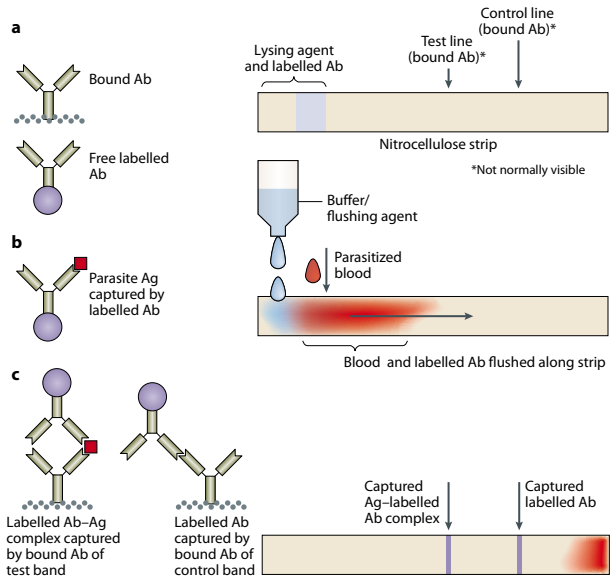
Despite WHO recommendations for laboratory-confirmed diagnosis of malaria infections prior to treatment in all cases (*2*), diagnosis is often made on clinical grounds (*5*). However, in most endemic areas malaria makes up a minority of 'malaria-like' febrile illness. Microscopy has been the cornerstone of diagnosis and is recommended for malaria diagnosis where its quality can be maintained, but 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 (*7-13*). 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 (*5*).

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 100 million tests or more financed in 2011[13] 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

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

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



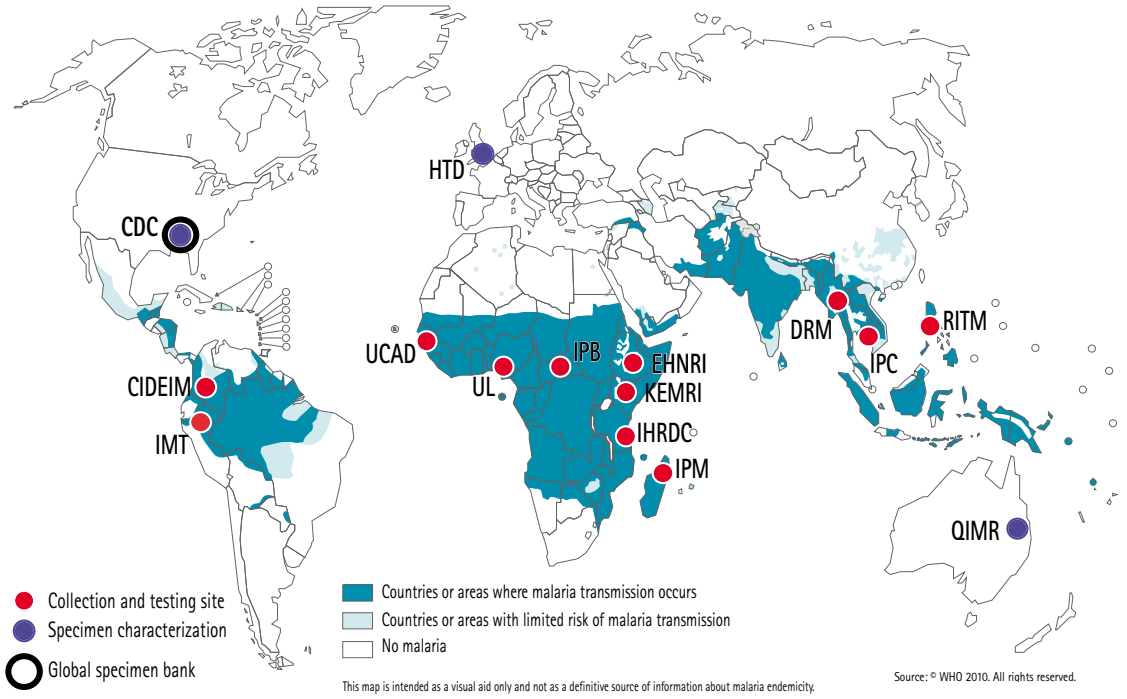
Mode of action of common malaria RDT format:

(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).

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 2011 overseeing the development of standard operating procedures (SOPs) for the programme (*16*). 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 report of the first and second rounds of Product Testing was released in 2009 and 2010, respectively *(3)*. This third report adds performance data on 27 new products and 23 re-submitted RDTs. Testing for Round 3 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. The majority of panel samples were retained from previous rounds. The results should be considered together with those from Round 1 and Round 2 *(3, 4)*.

4. OBJECTIVE

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 October 2009, 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 3 of the Product Testing Programme and the conditions for participation in the Evaluation Programme.[14] Requirements included: ISO 13485:2003 certification, supply of sufficient quantities of products (1100 tests from each of 2 lots), compliance with the product definition[15] and deadlines for document submission.

Twenty three manufacturers, including 62 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 3 was 50. Based on catalogue numbers and verification with manufacturers, 23 of the 50 products (46%) were previously submitted to either Round 1 or Round 2 (Table S3). After initial evaluation against the *P. falciparum* culture-derived panel (Phase 1), all products met minimum performance requirements[16] and proceeded to the full evaluation.

In summary, of the 50 products fully evaluated: 15 are designed to detect *P. falciparum* alone, 32 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria, and 3 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 3 (*16)*. 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 developed using a standard assessment format .

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

[14] *http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/call_for_testing_round3.htm*

[15] Working definition of a product can be found here on page 13: *http://www.wpro.who.int/internet/resources.ashx/RDT/docs/pdf_version/web3_QARDTreport.pdf* (accessed 8 September 2011)

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

Figure 3: Malaria RDT Product Testing Overview

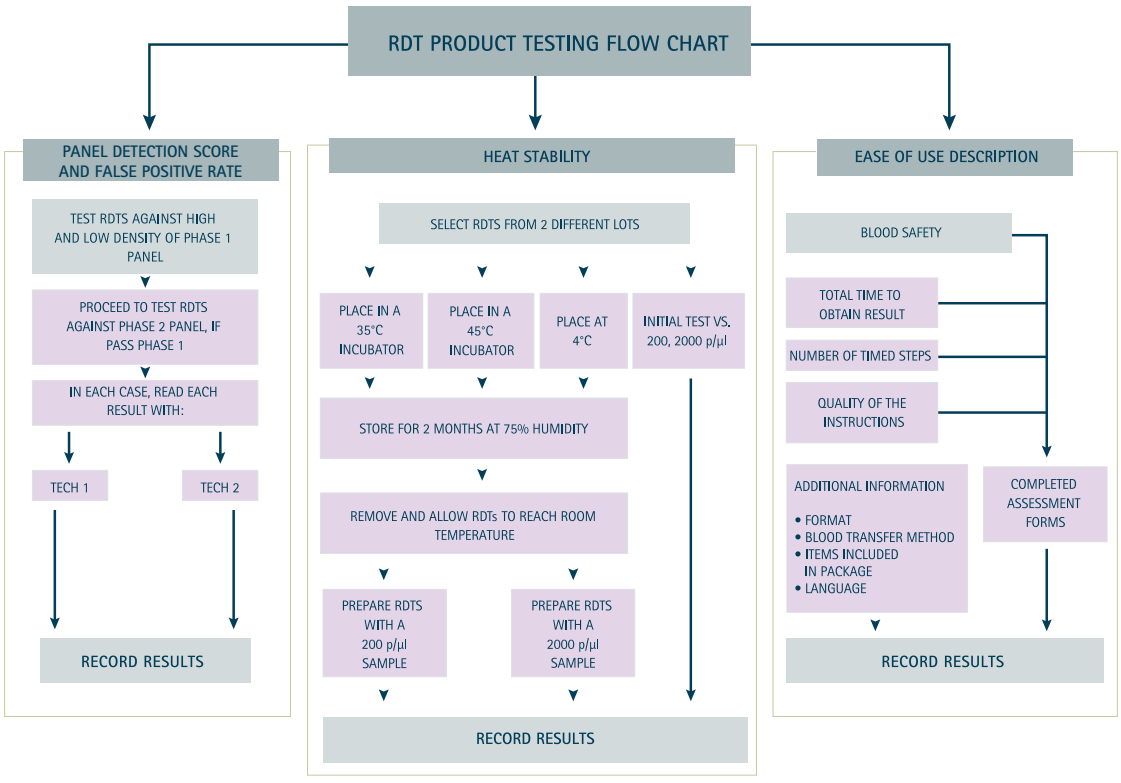


Table 1: Manufacturers and products accepted into Round 3 of WHO Malaria RDT Product Testing Programme

Manufacturer	Product Name	Catalogue Number[a]	Target antigen(s)		
ABON Biopharm (Hangzhou) Co. Ltd[b]	ABON Malaria Pan/P.f. Rapid Test Device (Whole Blood)	IMA-B402	HRP2	aldolase	
Access Bio, Inc.	CareStart ™Malaria pLDH 3 Line Test	G0121	pan pLDH	pf pLDH	
	CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	HRP2	pan pLDH	HCG
	CareStart™ Malaria Screen	G0231	Pf HRP2/Pf pLDH	pan pLDH	
ACON Biotech (Hangzhou) Co. Ltd[b]	Surestep™ Malaria Pf/Pan Rapid Test Device (Whole Blood)	IMA-T402	HRP2	aldolase	
AZOG,Inc	Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	pan pLDH	pf pLDH	
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	pv pLDH	HRP2	
	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R[c]	pan pLDH	HRP2	
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10	HRP2		
	NanoSign Malaria Pf/Pan Ag	RMAP10	HRP2	pan pLDH	
	NanoSign Malaria Pf/Pv Ag	RMAD10	pan pLDH	pf pLDH	
BioNote,Inc.	BIONOTE MALARIA P.f&P.v Ag Rapid Test Kit	RG19-12	HRP2	pv pLDH	
	BIONOTE MALARIA P.f&Pan Ag Rapid Test Kit	RG19-08	HRP2	pan pLDH	
	BIONOTE MALARIA P.f Ag Rapid Test Kit	RG19-11	HRP2		
Biosynex	IMMUNOQUICK CONTACT falciparum	0519K25	HRP2		
	IMMUNOQUICK CONTACT MALARIA +4	0525K25	HRP2	pan pLDH	
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (cassette)	522352[c]	HRP2		
Core Diagnostics	Core™ Malaria Pf	MAL-190020	HRP2		
	Core™ Malaria Pv/Pf	Mal-190022	HRP2	pv pLDH	
	Core™ Malaria Pan/Pv/Pf	Mal-190026	HRP2	pan pLDH	Pv pLDH
CTK Biotech, Inc.	OnSite Pf Ag Rapid Test	R0114C[c]	HRP2		
	OnSite Pf/Pan Malaria Ag Rapid Test	R0113C[c]	HRP2	pan pLDH	
	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C[c]	HRP2	Pv pLDH	
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024[c]	Pan pLDH	Pf pLDH	
Dima • Gesellschaft für Diagnostika mbH	Malaria Pan test	MAL-W23N-001	HRP2	aldolase	
ICT Diagnostics	ICT Diagnostics Malaria Combo	ML02[c]	HRP2	aldolase	
	ICT Diagnostics Malaria Dual	ML03	HRP2	pan pLDH	
	ICT Diagnostics Malaria P.f	ML01[c]	HRP2		
InTec Products, Inc.	Advanced Quality™ One Step Malaria P.f/P.v Tri-line Test	ITP11003 TC40	HRP2	pv pLDH	
	Advanced Quality™ One Step Malaria P.f Test	ITP11002 TC40[c]	HRP2		
J. Mitra & Co. Pvt. Ltd.	Advantage Malaria Card	IR211025	HRP2	Pv pLDH	
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for *P. falciparum* Malaria (Ver. 3)	30301025[c]	HRP2		
	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver. 3)	30302025[c]	HRP2		
Orgenics Ltd.[b]	Clearview® Malaria pLDH	70884025	pan pLDH		
Standard Diagnostics Inc.[b]	SD BIOLINE Malaria Ag	05FK40[c]	pan pLDH	pf pLDH	
	SD BIOLINE Malaria Ag P.f/Pan	05FK60[c]	HRP2	pan pLDH	
	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	HRP2	Pf pLDH	
Span Diagnotics Ltd.	ParaHIT® - f (Device)	55IC102-10[c]	HRP2		
	ParaHIT® - f (Dipstick)	55IC101-10[c]	HRP2		
SSA Diagnostics & Biotech Systems	diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	pan pLDH		
	diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	HRP2	pan pLDH	
	diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	HRP2	pan pLDH	Pv pLDH
Vision Biotech (Pty) Ltd.[b]	Clearview® Malaria Combo	VB11[c]	HRP2	aldolase	
	Clearview® Malaria Pf	VB01[c]	HRP2		
	Clearview® Malaria Dual Test Device	VB20[c]	HRP2	pan pLDH	
Guangzhou Wondfo Biotech Co. Ltd.	One Step Malaria P.f./Pan Whole Blood Test	W56-C[c]	HRP2	pan pLDH	
	One Step Malaria P.f Test	W37-C[c]	HRP2		
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025[c]	HRP2	aldolase	
	Parabank™ Device - Rapid test for Malaria Pan	50301025[c]	pan pLDH		
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025[c]	HRP2	pan pLDH	

[a] Some products may include different catalogue numbers for different box sizes, contact manufacturers for details.

[b] Since enrolment in WHO Malaria Product Testing Round 3, these have become Alere ™ companies.

[c] These products have also been submitted to previous rounds of WHO Malaria RDT Product Testing (Round 1 or 2). For details on all product resubmissions see Table S3.

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[17]) 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 *(16-17)*. Characterization results can be found on the WHO/WPRO RDT and FIND websites[18]

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 (*18*). All samples have their geographical origin recorded.

[17] 8 (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[18] *http://www.wpro.who.int/sites/rdt/who_rdt_evaluation/call_for_testing_round3.htm - http://www.finddiagnostics.org/*

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, 3 with Type A, and 2 with Type C HRP2 sequence. All specimens were derived from the culture bank of CDC, and diluted in O+ USA donor blood *(16)*.

Wild-type parasite panel

The parasite-positive wild-type (clinical) panel consisted of samples from 99 cases of *P. falciparum* and 35 cases of *P. vivax*, derived from 11collection 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 *(17)*. After dilutions and cryopreservation, samples were transferred to the global 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 3, 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 (Philippines, Madagascar, Senegal, Nigeria and Kenya), having

Figure 4a: Origin of Phase 2 *P. falciparum* wild type (clinical) samples (n=99)

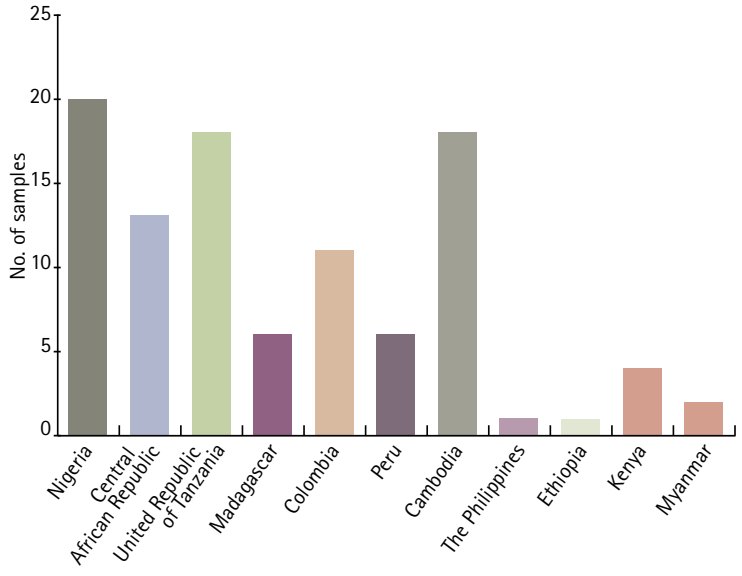
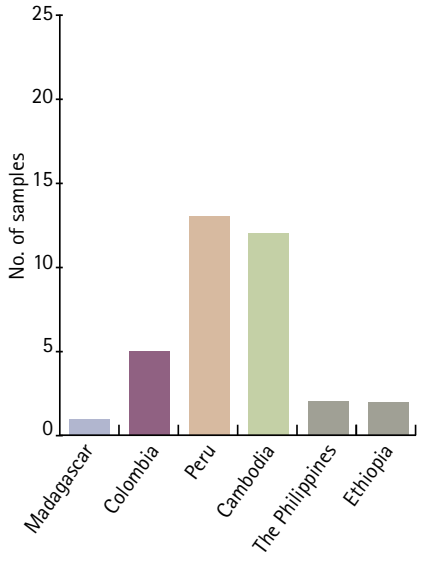


Figure 4b: Origin of Phase 2 *P. vivax* wild type (clinical) samples (n=35)



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/RndThreeProdTestEvalPanel_Pub.pdf* (accessed 13 September,2011) .

5.4. RDT registration

The receipt of each shipment of RDTs at the evaluation centre 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 at $\leq 25°C$ 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. Products not designed to detect *P. falciparum* were excluded from Phase 1. To move to the full evaluation (Phase 2), a product evaluated in Phase 1 must have achieved an 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 parasite-positive and parasite-negative panel was comprised of 99 *P. falciparum*, 35 *P. vivax* at two parasite densities (200 parasites/µl and 2000 (or 5000)[19] 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 *(16)*.

[19] Eight (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

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

Nature of negative sample[a]	No.
Clean-negative[b]	50
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)	9
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)	10

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

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

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 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.

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.

6. DATA MANAGEMENT

The receipt of products was hand recorded in an 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 reporting) and CDC (PCR) and then entered directly into Excel followed by importation into a specially developed database.

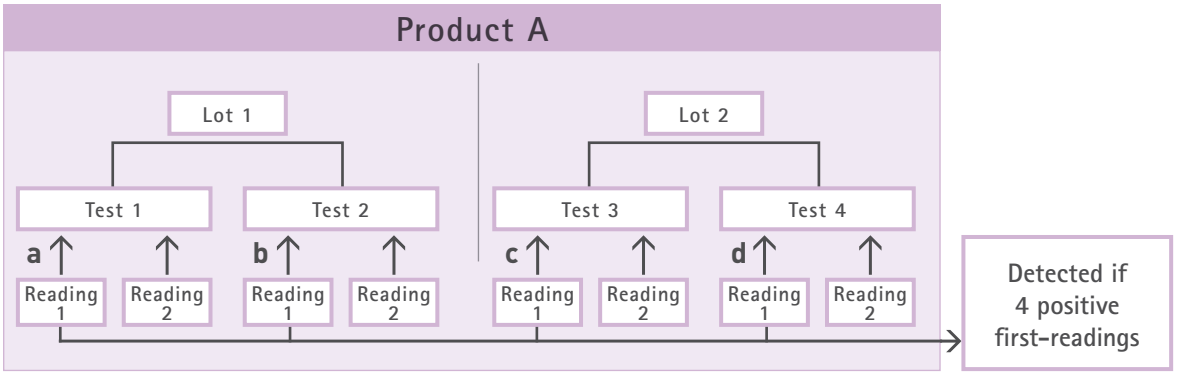
The results of the product panel testing and heat stability testing conducted at the CDC were recorded on report forms by each technician individually, as per the SOP. These results were double-data entered, and analysed for discrepancies.

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 and accompanying raw data were distributed to manufacturers' in July 2011, for a 60 days review period prior to publication of the final report.

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.

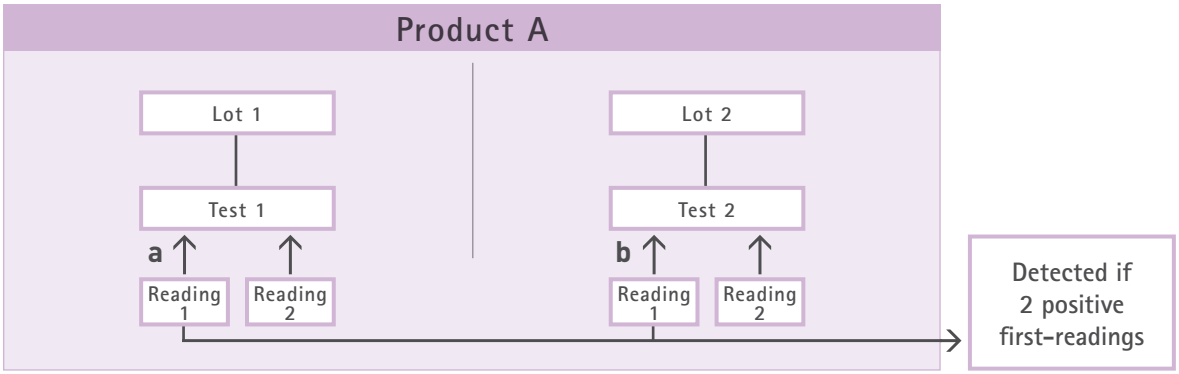


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[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

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 2 *(16)*. 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 $\leq 25°C$; 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. 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 specimen bank samples:

SOPs were established for the preparation of all specimen bank samples *(17)*. 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 ofMalaria and Parasitic Diseases, CDC, is one of the major operating components of the Department of Health and Human Services (HHS) of the USA. The laboratory holds Clinical Laboratory Improvement Amendments (CLIA) accreditation and is monitored by internal quality management systems (QMS) programmes.

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 (eg. rheumatoid factor, anti-nuclear antibodies, anti-mouse antibodies) (Table 2).

9.3. Band intensity

All positive tests 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)[20] as the percentage recorded at that level.

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

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.

[20] 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.

9.6. Heat (thermal) stability

The results of heat stability testing are reported as the number of positive tests from two lots returned at each parasite density (maximum score 30 against 200 parasites/µl samples; 10 against 2000 parasites/µl samples)[21] and mean band intensity (for positive tests only) 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.

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. 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 *(20)*.

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 *(19)*.

[21] 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.

11. RESULTS

11.1. Summary

In Round 3 of the WHO Malaria RDT Product Testing, 50 products were evaluated against *P. falciparum* culture samples, and all 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 April 2010 and February 2011 over 60,000 tests were performed at the CDC.

The results of the evaluation reveal the following key outcomes:

i) The overall range of results including PDS [formerly 'Detection Rate'], positivity rate, false-positive rates and heat stability, were similar to those reported in Round 1 and Round 2 *(3,4)* . However, overall *P.falciparum* and *P. vivax* PDS mean and median were higher against the low parasite density samples compared to earlier rounds.

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 and 2.

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) *P. falciparum* tests targeting HRP2 antigen demonstrated the highest PDS for *P. falciparum*, and had a higher average PDS than tests targeting pLDH, but there was some overlap.

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

vi) Test performance 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. Data is 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.

Table 3: Summary Phase 1 performance of 50 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							
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	95.0	100.0	N/A	N/A	0.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	90.0	100.0	N/A	N/A	0.8
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	95.0	100.0	N/A	N/A	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	N/A	N/A	0.8
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	95.0	100.0	N/A	N/A	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	80.0	100.0	N/A	N/A	0.0
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	85.0	100.0	N/A	N/A	2.5
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	85.0	95.0	N/A	N/A	0.8
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	65.0	100.0	N/A	N/A	0.0
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	85.0	100.0	N/A	N/A	0.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	95.0	100.0	N/A	N/A	0.8
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	100.0	100.0	N/A	N/A	0.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	80.0	100.0	N/A	N/A	0.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	80.0	100.0	N/A	N/A	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[c]	05FK90	Standard Diagnostics Inc.	95.0	100.0	N/A	N/A	0.0
Pf and Pan							
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	70.0	90.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	95.0	100.0	0.0	0.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	85.0	100.0	0.0	0.0	0.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	90.0	100.0	1.3	0.0	0.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	95.0	100.0	1.3	0.0	0.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	80.0	100.0	0.0	0.0	0.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	85.0	100.0	0.0 (79)	0.0 (39)	1.7
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	100.0	100.0	0.0	0.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	85.0	100.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	80.0	100.0	0.0	0.0 (39)	0.8
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.0	100.0	0.0 (79)	0.0	0.8
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	65.0	100.0	0.0	0.0	0.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	100.0	100.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0	85.0	6.3	2.5	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	95.0	100.0	0.0 (76)	0.0 (36)	6.7
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	90.0	100.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	85.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	30.0	100.0	0.0 (79)	0.0 (39)	1.7
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	90.0	100.0	0.0	0.0	0.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	35.0	100.0	22.5	0.0	0.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	100.0	100.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	100.0	1.3	0.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	100.0	100.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	95.0	100.0	0.0	0.0	0.0

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 and Pv							
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	100.0	100.0	0.0	0.0	0.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	85.0	100.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	95.0	100.0	0.0 (79)	0.0	0.8
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	0.0 (79)	0.0	0.8
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	85.0	100.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	80.0	100.0	0.0	0.0	0.0
Pf, Pan and Pv							
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	100.0	95.0	0.0	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	100.0	100.0	0.0 (79)	0.0	0.8
Pan only							
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	90.0	100.0	N/A	N/A	0.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	5.0	100.0	N/A	N/A	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	10.0	100.0	N/A	N/A	0.0

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

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

RESULTS

Table 4: Summary Phase 2 performance of 50 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=1204)
			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=99)	Pv samples (n=35)	Pf samples (n=99)	Pv samples (n=35)	False positive non Pf infection[c] (n=396)	False positive Pf infection[d] (n=160)	False positive non Pf infection[c] (n=198)	False positive Pf infection[d] (n=80)	False positive *Plasmodium spp.* Infection (n=200)	
Pf only												
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	93.9	N/A	100.0	N/A	N/A	40.0	N/A	35.7	38.5	0.1
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	85.9	N/A	99.0	N/A	N/A	0.0	N/A	1.4	2.0	0.1
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	83.8	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	N/A	100.0	N/A	N/A	0.0	N/A	0.0	1.0 (198)	0.3
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	86.9	N/A	98.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	N/A	100.0	N/A	N/A	3.6 (139)	N/A	1.4	4.0 (199)	0.3
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.3
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	67.7	N/A	97.0	N/A	N/A	0.0	N/A	2.9	1.0	0.2
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	60.6	N/A	98.0	N/A	N/A	0.7 (139)	N/A	0.0	0.0	0.2
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	85.9	N/A	100.0	N/A	N/A	0.7	N/A	0.0	3.5	0.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	96.0	N/A	99.0	N/A	N/A	0.0 (138)	N/A	1.5 (68)	1.5	0.9
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	89.9	N/A	98.0	N/A	N/A	0.0	N/A	1.4	0.5	0.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	84.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	0.0	0.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	80.8	N/A	99.0	N/A	N/A	0.0	N/A	1.4	2.5	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[f]	05FK90	Standard Diagnostics Inc.	87.9	N/A	100.0	N/A	N/A	0.0	N/A	0.0	2.0	0.0
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
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	93.9	88.6	99.0	100.0	0.0	0.0	0.0	0.0	3.0 (199)	0.1
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
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
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
Clearview® Malaria Combo	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
Clearview® Malaria Dual Test Device	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
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
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	84.9	8.6	98.0	91.4	0.0	3.6	0.0	5.7	2.5	0.0
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
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	98.0	94.3	1.7 (395)	5.1 (138)	0.0	0.0	2.0	0.3
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
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	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
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
Malascan™ Device - Rapid test for Malaria Pf/Pan	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
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	77.8	0.0	100.0	91.4	0.0	2.9	0.0 (197)	2.9	0.5	0.0

Product	Catalogue number	Manufacturer	Panel Detection Score[b]				False positive rates (%)				Total false positive rates[e] (%)	Invalid rate (%) (n=1204)
			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=99)	Pv samples (n=35)	Pf samples (n=99)	Pv samples (n=35)	False positive non Pf infection[c] (n=396)	False positive Pf infection[d] (n=160)	False positive non Pf infection[c] (n=198)	False positive Pf infection[d] (n=80)	False positive *Plasmodium spp.* Infection (n=200)	
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
One Step Malaria P.f/Pan Test	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
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	83.8	85.7	100.0	100.0	1.3	0.0	0.0	0.0	27.5	0.0
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
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	89.9	45.7	97.0	88.6	1.0 (394)	2.1	0.0 (197)	7.1	3.5 (199)	0.4
SD BIOLINE Malaria Ag P.f/Pan	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
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0
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
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
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
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
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
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	84.9	97.1	100.0	100.0	5.3	0.0	6.1	0.0	28.0	0.0
Pf, Pan and Pv												
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
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
Pan only												
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	81.8	85.7	99.0	100.0	N/A	N/A	N/A	N/A	13.5	0.5
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	N/A	N/A	N/A	N/A	0.0	0.3
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	N/A	N/A	N/A	N/A	0.5	0.2

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

[a] 8 (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *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 was : pf-pLDH (17.2% at 200p/µl; 97% at 2000p/µl) and pf-HRP2 (87.9% at 200p/µl; 100% at 2000p/µl)

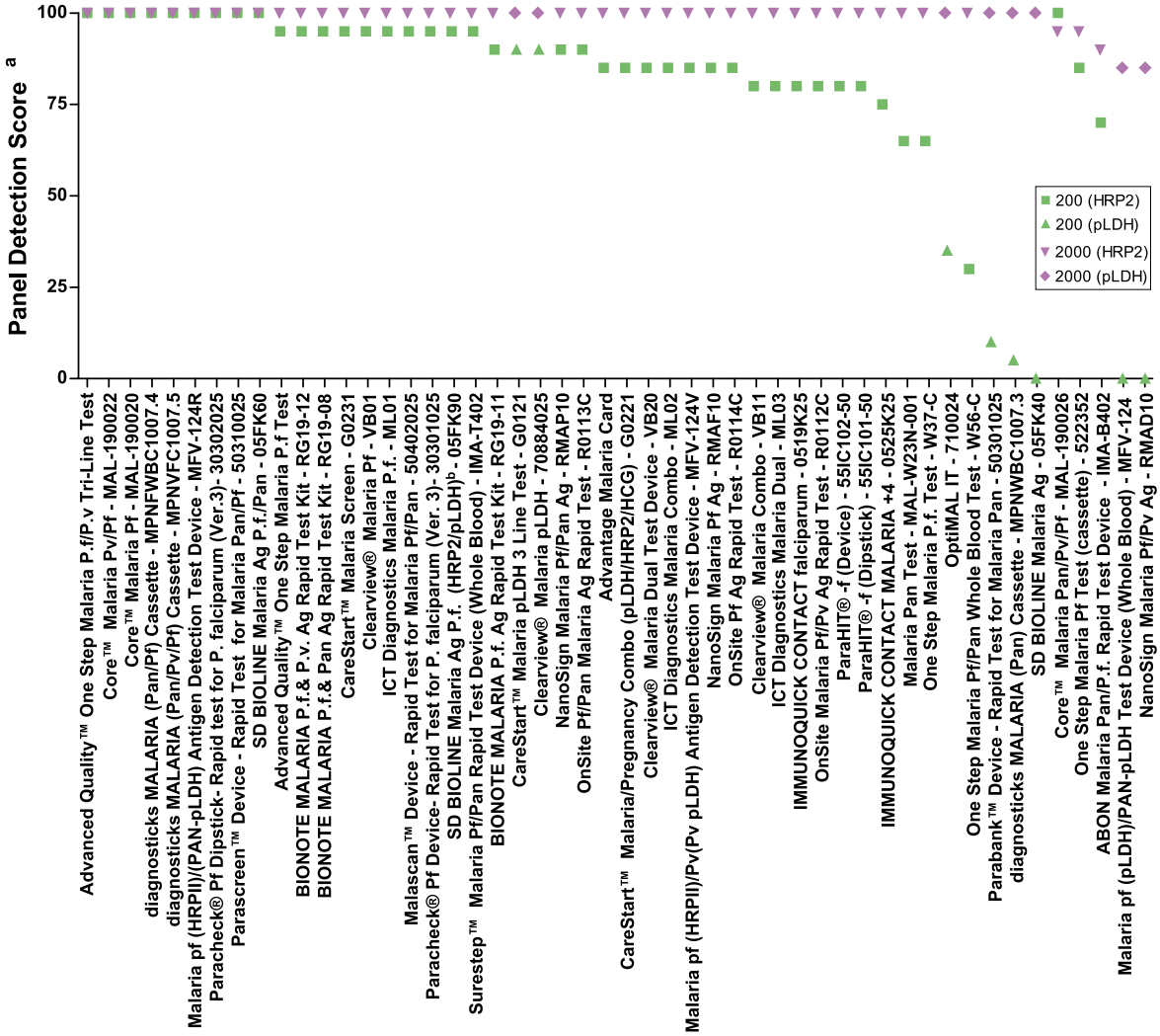
Detection rate (%)	≥95	85-94	50-84	< 50
False positive rate (%)	<2	2-5	6 -10	>10
Invalid rate (%)	<1% of tests conducted	1-2% of tests conducted	2-5% of tests conducted	>5% of tests conducted

RESULTS

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

The majority (94%) of tests 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). All products had a PDS ≥ 80% on high parasite density samples and therefore, proceeded 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.

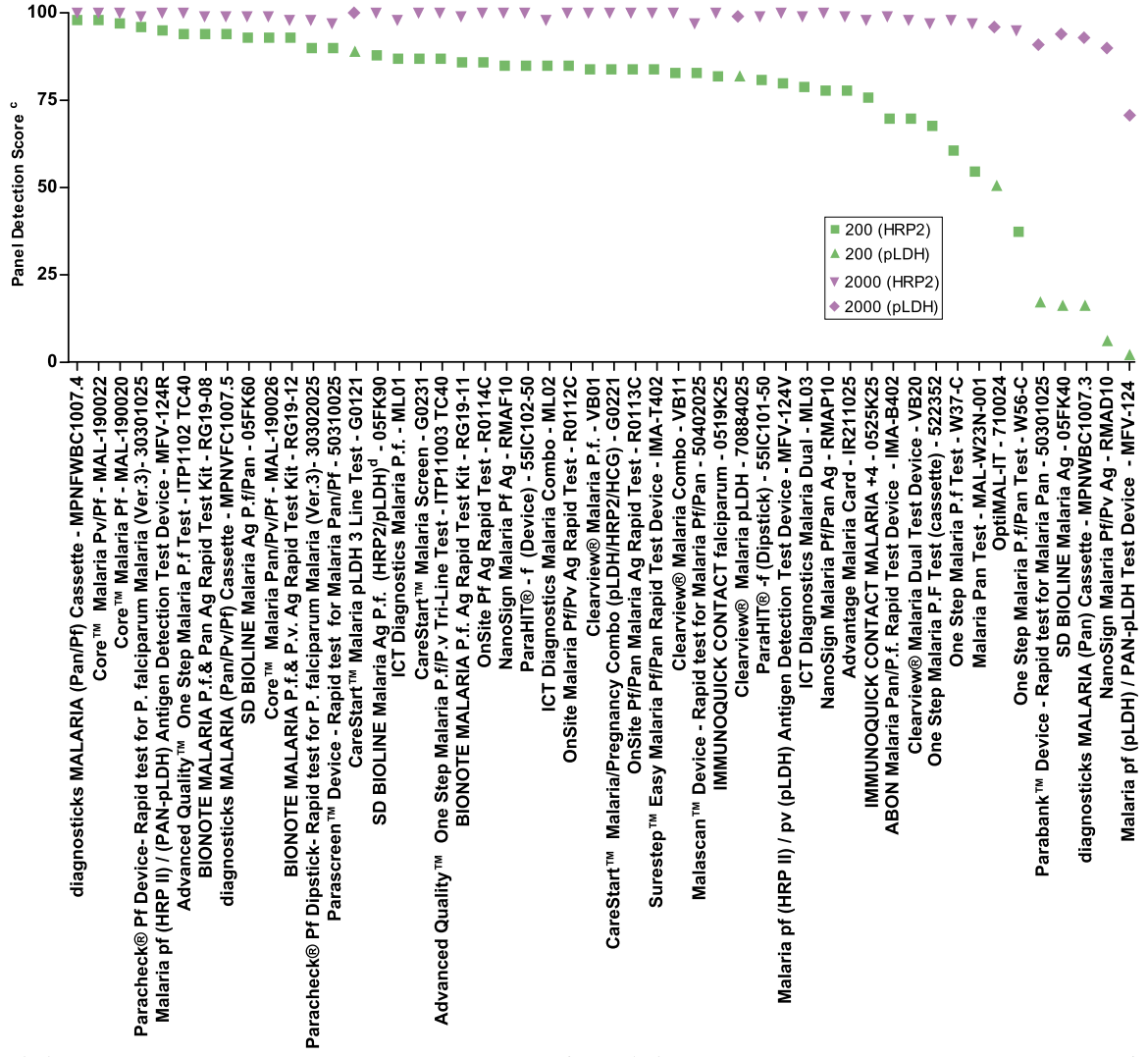
[b] Refer to Table A3.1 for individual panel detection scores for HRP2 and pf-pLDH test lines

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

11.3.1. *P. falciparum* detection

All 50 products in Round 3 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; 90%) had a panel detection score ≥95% of *P. falciparum* samples at high parasite densities but only 5 tests (10%) had this high a PDS at low parasite density (200 parasites/µl). All of these products targeted HRP2. All fifteen products specific for *P. falciparum* alone achieved PDS of ≥50% 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] 8 (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[b] Phase 2 evaluation panel consisted of 99 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;

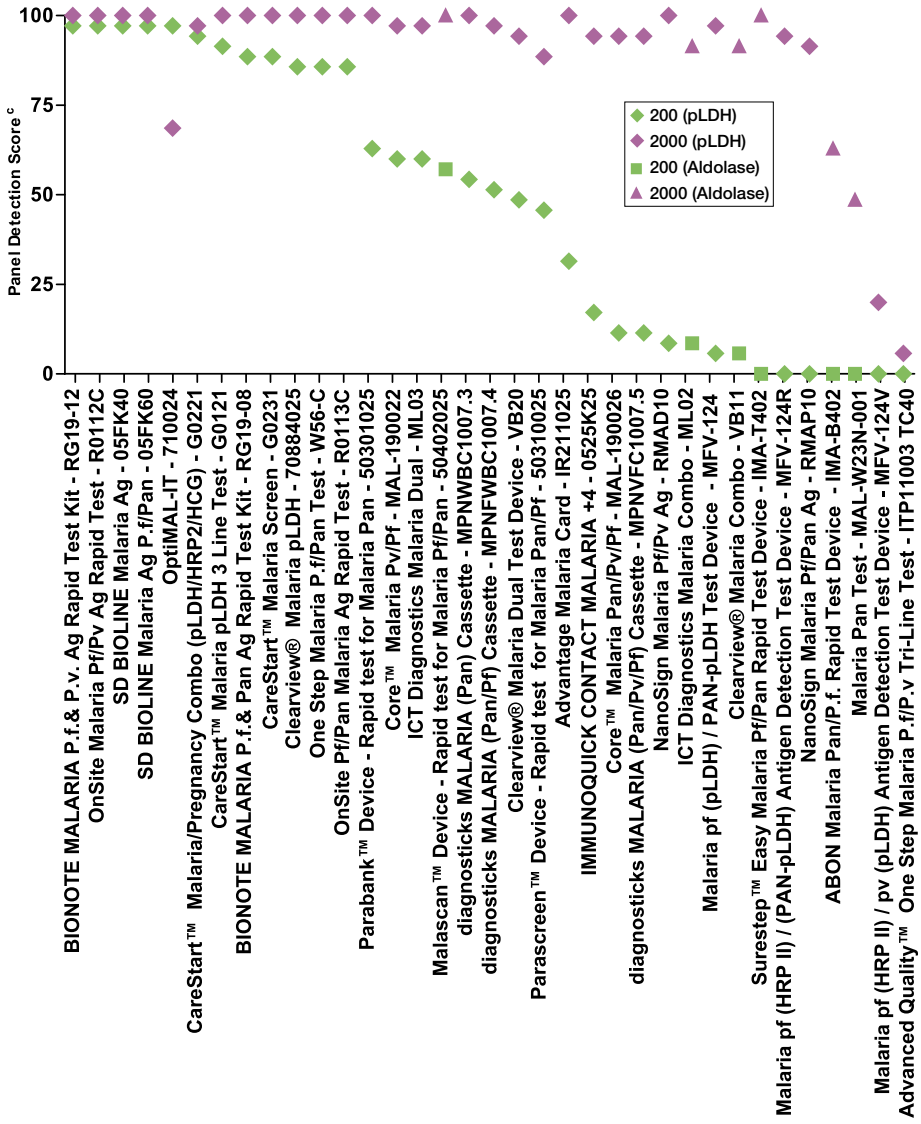
[c] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive;

[d] Refer to Table 4 for individual panel detection scores for HRP2 and pf-pLDH test lines

11.3.2. *P. vivax* detection

Figure 9 illustrates, that of the 35 products designed to detect *P. vivax* most detected high parasite densities (2000 (or 5000) parasites/µl) consistently, and several achieved a high PDS against 200 parasite/µL samples. However, 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 seven products (20%) had panel detection scores ≥ 90% and 18 and 12 products had a PDS of ≥50% and ≥ 75%, respectively. (Table 4)

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] 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl;

[b] Phase 2 evaluation panel consisted of 35 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

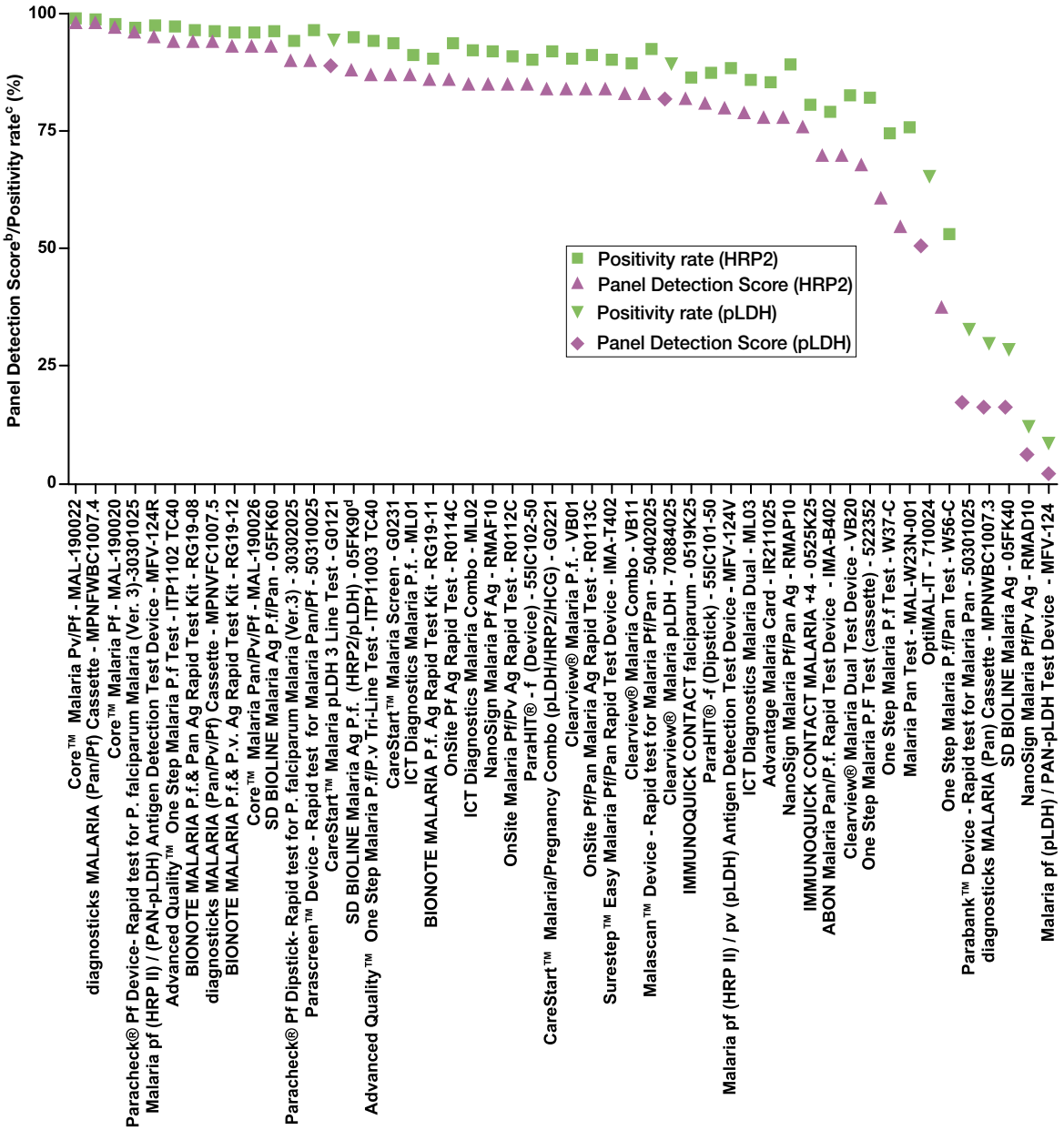
11.3.3. Combined detection of *P. falciparum* and *P. vivax*

Considering the 32 combination tests, 14 (44%) had a PDS of ≥50% and 8(25%) 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. Two of the three pan-specific only tests had substantially better panel detection scores for *P. vivax* than *P. falciparum,* particularly against low parasite density samples.

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 and positivity rate at 200 parasites/µl[a]



[a] Phase 2 evaluation panel consisted of 99 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;

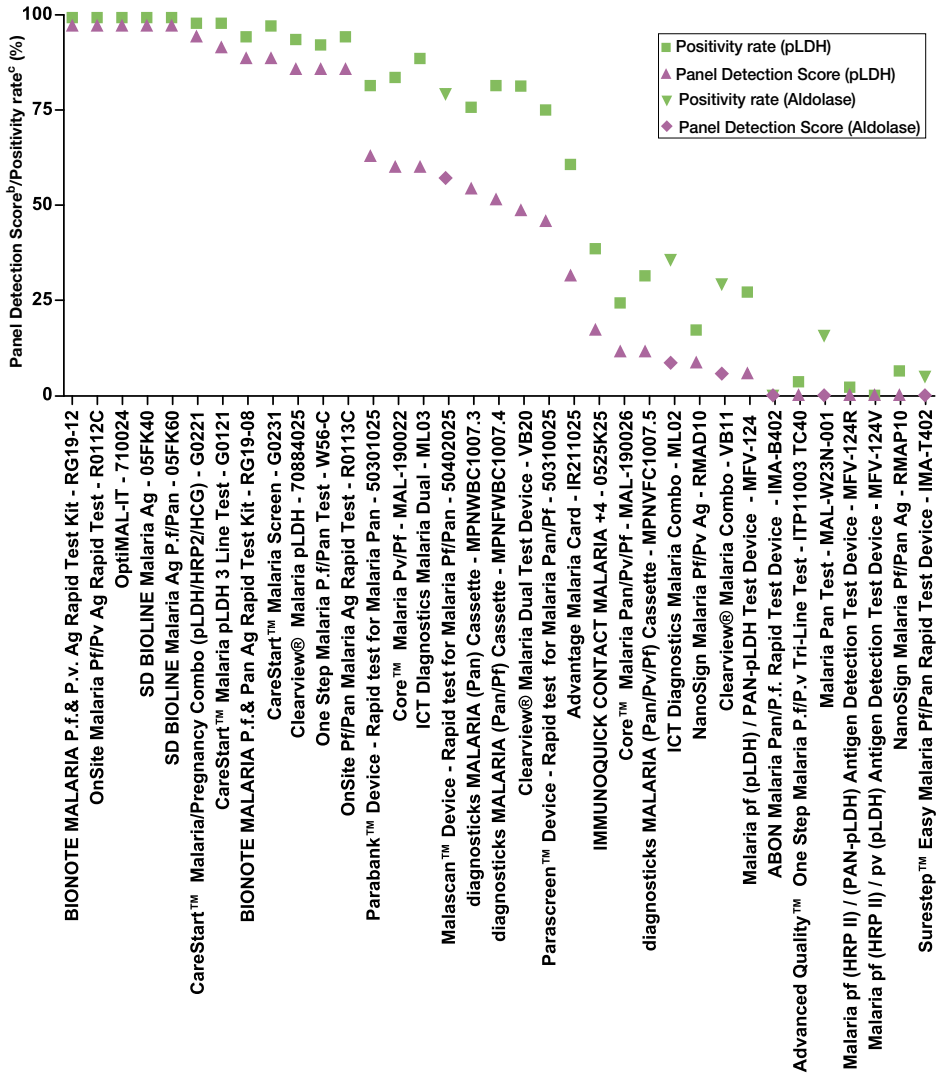
[c] the total number of times a test returned a positive result/total number of times tested;

[d] Refer to Table 4 for individual panel detection scores for HRP2 and pf-pLDH test lines

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; suggesting that, as expected, strong test bands are interpreted more reliably.

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



[a] Phase 2 evaluation panel consisted of 35 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/total number of times tested

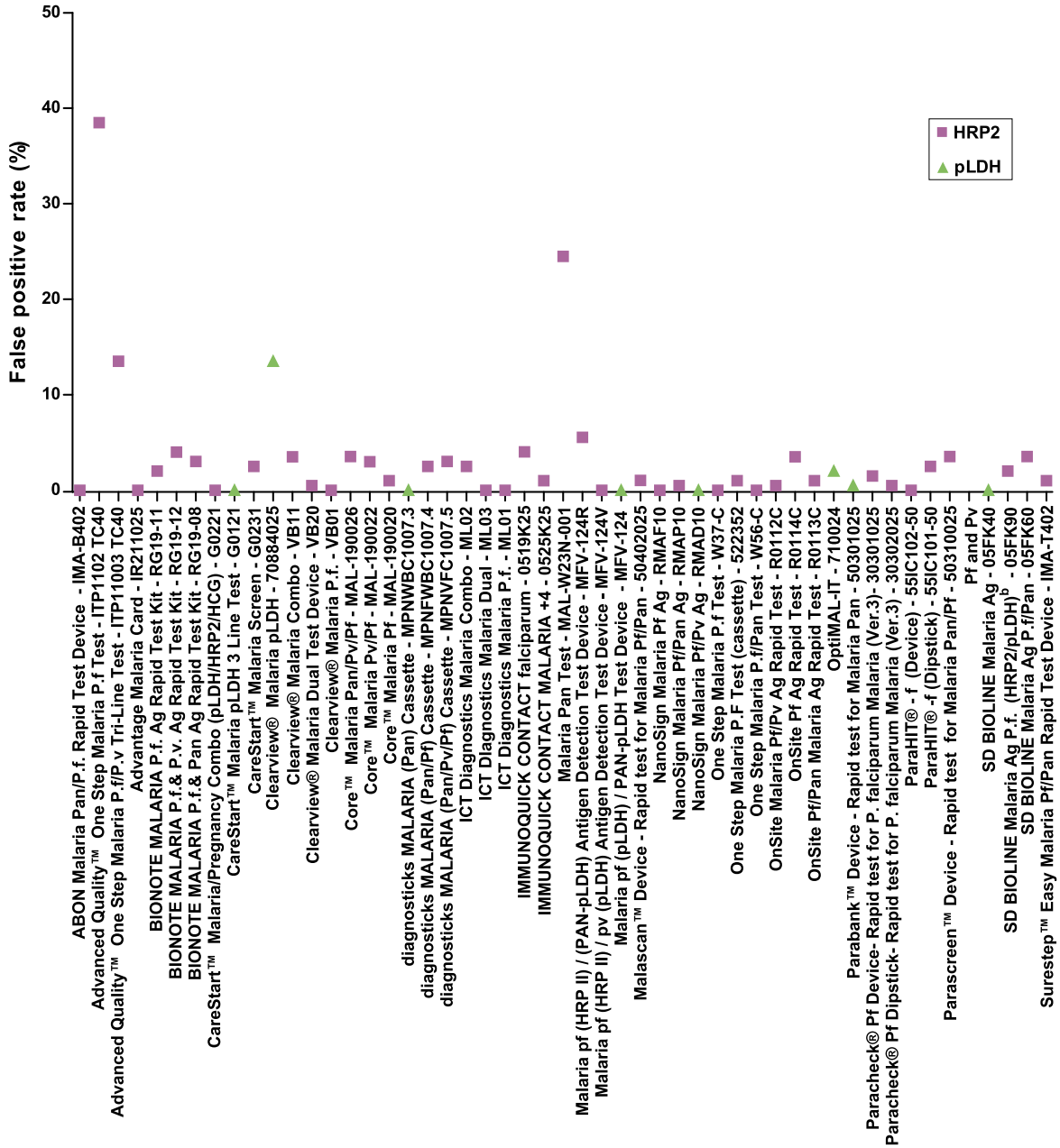
11.3.6. False-positive rates

Overall false-positive rates were low, with only six tests having rates >10% on clean-negative samples, on any test line (Figures 12, 13). High false-positive rates were seen with some tests against parasite-negative blood with all four immunological blood abnormalities, in the panel 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).

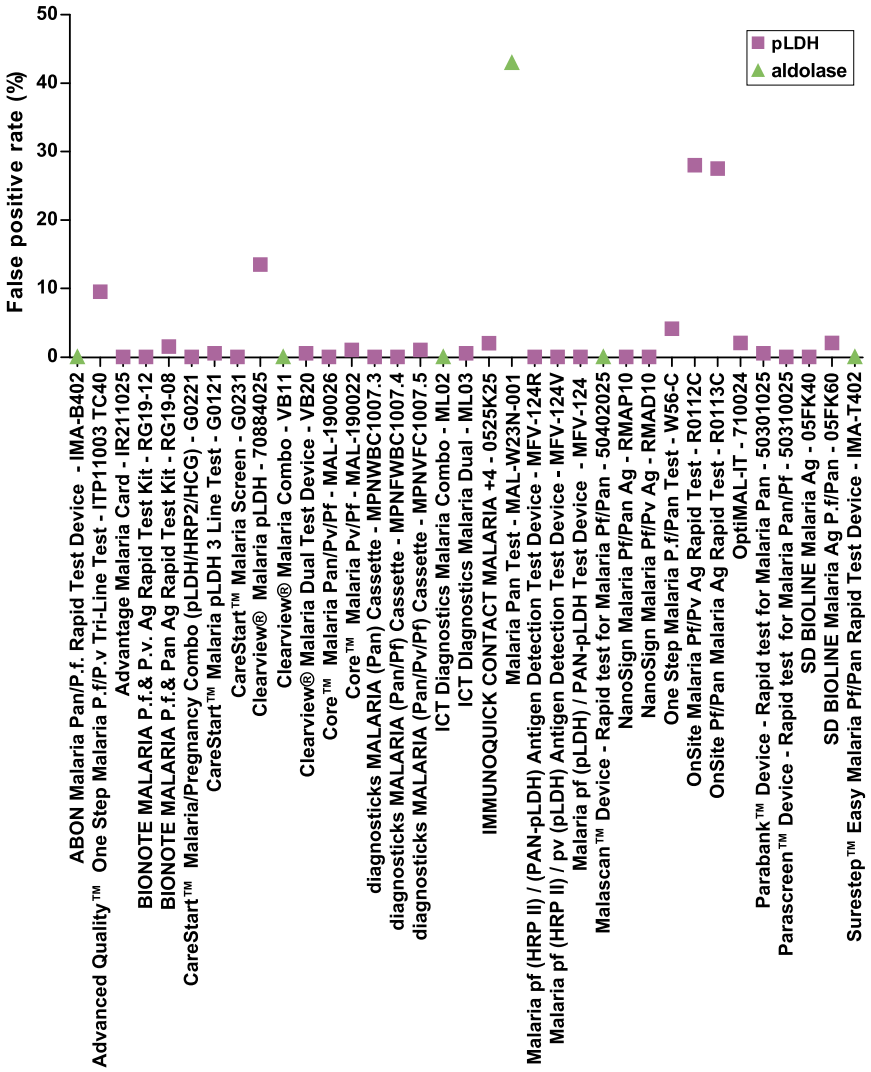
Figure 12: Phase 2 *P. falciparum* (*P. falciparum* test line) false positive rate against clean negative samples[a]



[a] Phase 2 evaluation panel included 100 *Plasmodium spp.* negative samples of which 50 were clean negatives from healthy volunteers with no known current illness or blood abnormality;

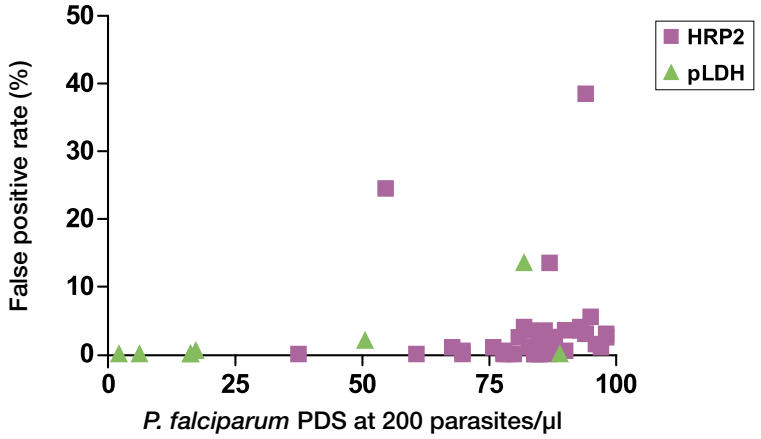
[b] Refer to Table A4.7 for individual false positive rates for HRP2 and pf-pLDH test lines

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



[a] Phase 2 evaluation panel included 100 *Plasmodium spp.* negative samples of which 50 were clean negatives, from healthy volunteers with no known current illness or blood abnormality

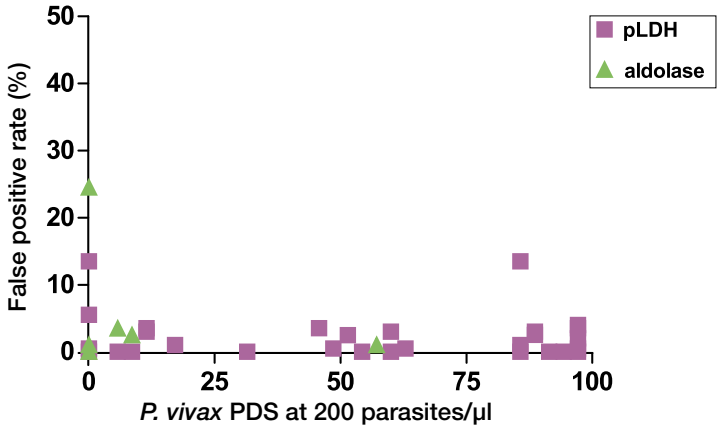
Figure 14: Phase 2 *P. falciparum* false positive rate[a] versus *P. falciparum* panel detection score[b] at low (200) parasite density (parasites/µl)



[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 was used as the reference sample for heat stability testing. Variations in baseline performance reflect inter-test variation as 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, 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 base-line positivity less than 100% showed unpredictable variation in positivity rates on subsequent testing after two months, consistent with test lines on the borderline of visibility. 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 in previous rounds, some products showed an improved performance with incubation (Figures 17, 18, 20, 22 23). Overall, the stability of pLDH-detecting test lines was lower than that for HRP2-detecting test lines, but some tests did exhibit good stability of pLDH test lines, indicating heat-stable combination tests.

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 50 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

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														
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	30.0	30.0	26.0	N/A	N/A	N/A	10.0	9.0	8.0	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	30.0	30.0	29.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	29.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	19.0	0.0	0.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	30.0	28.0	27.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	29.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	30.0	29.0	30.0	N/A	N/A	N/A	10.0	10.0	9.0	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	30.0	30.0	17.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)a	05FK90	Standard Diagnostics Inc.	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Pf and Pan														
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	30.0	24.0	27.0	0.0	0.0	0.0	10.0	10.0	10.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	30.0	30.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	9.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	30.0	30.0	30.0	30.0	30.0	30.0	10.0	10.0	10.0	10.0	10.0	10.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	30.0	30.0	30.0	30.0	30.0	30.0	10.0	10.0	10.0	10.0	10.0	10.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	30.0	30.0	28.0	30.0	30.0	28.0	10.0	10.0	10.0	10.0	10.0	10.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	9.0	2.0	0.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	30.0	30.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	5.0	9.0	2.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	30.0	30.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	9.0	9.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	30.0	30.0	29.0	0.0	0.0	0.0	10.0	10.0	9.0	9.0	3.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	30.0	30.0	28.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	8.0	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	5.0	5.0	10.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	18.0	10.0	7.0	4.0	16.0	12.0	10.0	10.0	9.0	1.0	6.0	4.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	0.0	0.0	0.0

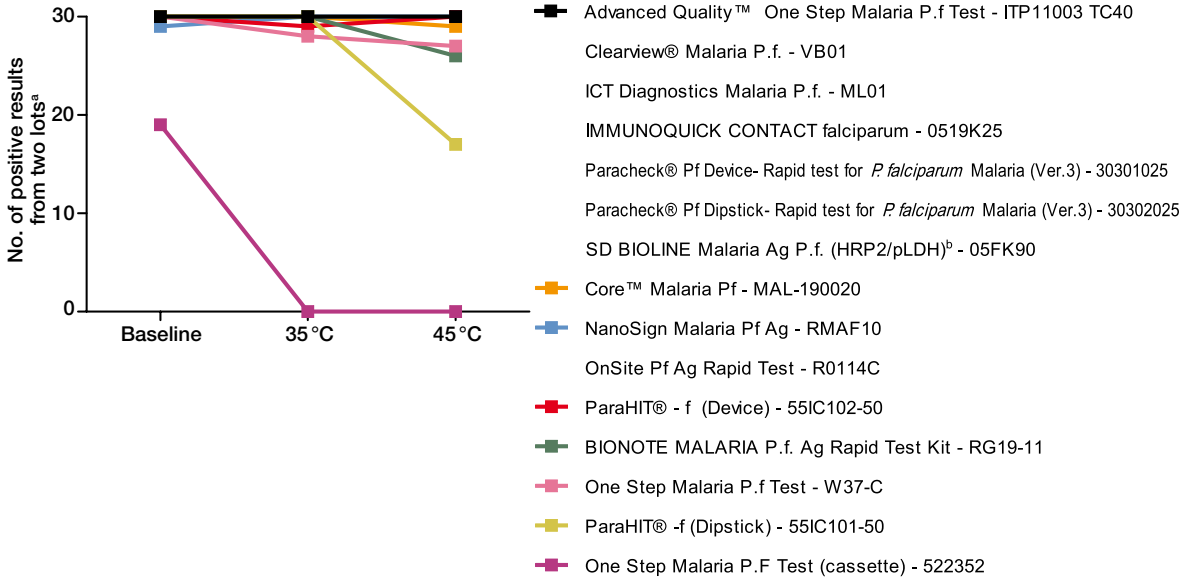
Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)		
			200 parasites/µl			200 parasites/µl			2000 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		
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	1.0	0.0	0.0	0.0	0.0	0.0	4.0	1.0	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	29.0	30.0	29.0	0.0	0.0	2.0	10.0	10.0	10.0	10.0	10.0	10.0
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	9.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	14.0	4.0	8.0	0.0	11.0	22.0	10.0	10.0	10.0	7.0	8.0	10.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	30.0	30.0	30.0	1.0	20.0	25.0	10.0	10.0	10.0	10.0	10.0	8.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	0.0	0.0	10.0	9.0	0.0	10.0	9.0	0.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	9.0	10.0	10.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	30.0	29.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	7.0	9.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	10.0	8.0	9.0	8.0	2.0	9.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (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
Pf and Pv														
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	29.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	30.0	29.0	29.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	30.0	29.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	30.0	30.0	29.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	30.0	30.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0	N/A	N/A	N/A
Pf, Pan and Pv														
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	30.0	30.0	30.0	0.0	0.0	0.0	10.0	9.0	10.0	8.0	5.0	7.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	29.0	30.0	28.0	0.0	0.0	0.0	10.0	10.0	10.0	7.0	0.0	5.0
Pan only														
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	N/A	N/A	N/A	29.0	28.0	30.0	N/A	N/A	N/A	10.0	10.0	10.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	0.0	0.0	0.0	N/A	N/A	N/A	8.0	10.0	8.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	0.0	0.0	0.0	N/A	N/A	N/A	9.0	10.0	10.0

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

[a] Results presented in the table are based on stability of a pf test line (either pf-HRP2 or pf-pLDH). Results based on stability of individual test lines on 200p/µl samples were : pf-pLDH (0/30 at baseline and post 60 d incubation at 35°C, 45°C) and pf-HRP2 (30/30 at baseline and post 60 d incubation at 35°C, 45°C)

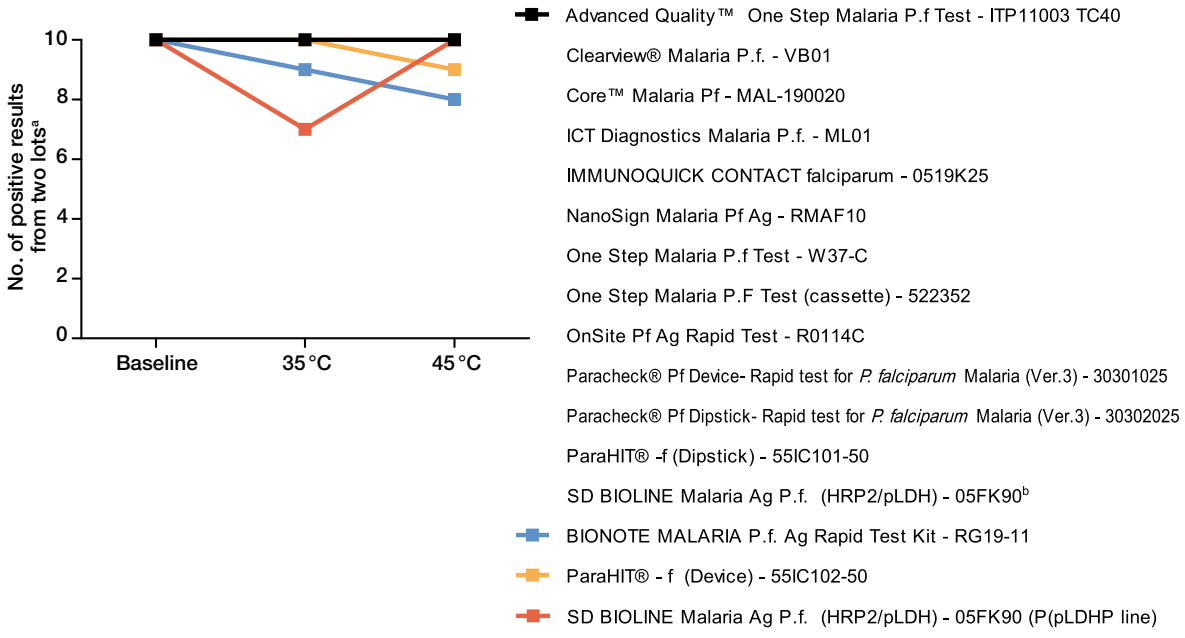
12.1. *P. falciparum* test lines

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.



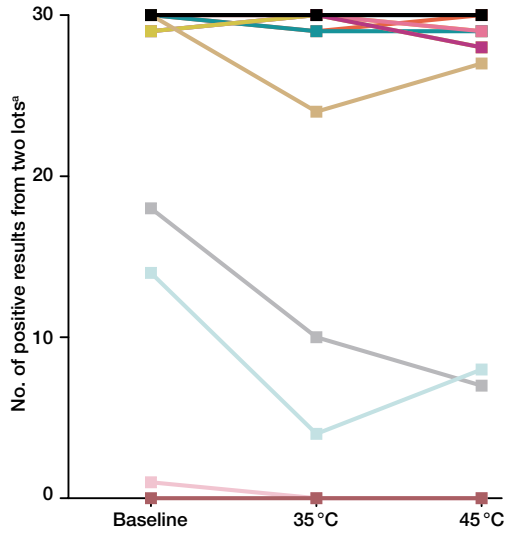
[a] Maximum score is 30 (15 tests x 2 lots);
[b] Refer to Table A4.11 for individual HRP2 and pf-pLDH test line performance

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);
[b] Refer to Table A4.12 for individual HRP2 and pf-pLDH test line performance

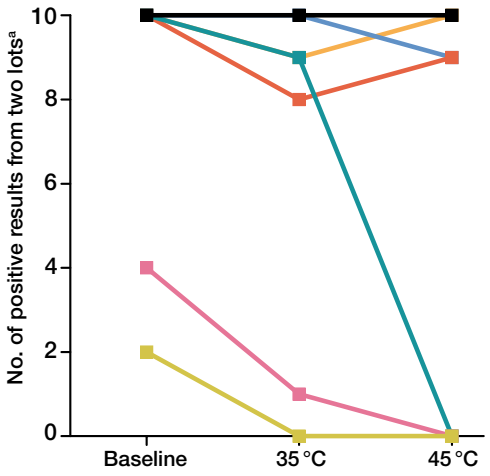
Figure 18: Heat stability of *P. falciparum* specific test line in combination tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



- CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
- CareStart™ Malaria pLDH 3 Line Test - G0121
- Clearview® Malaria Combo - VB11
- Core™ Malaria Pan/Pv/Pf - MAL-190026
- Core™ Malaria Pv/Pf - MAL-190022
- IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
- Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
- NanoSign Malaria Pf/Pan Ag - RMAP10
- OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
- OnSite Pf/Pan Malaria Ag Rapid Test - R0113C
- Parascreen™ Device - Rapid test for Malaria Pan/Pf - 50310025
- Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMT-T402
- BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
- Clearview® Malaria Dual Test Device - VB20
- diagnosticks MALARIA (Pan/Pf) Cassette - MPNFWBC1007.4
- ICT Diagnostics Malaria Combo - ML02
- Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
- Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test - ITP11003 TC40
- BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit - RG19-12
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60
- Advantage Malaria Card - IR211025
- Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
- diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
- CareStart™ Malaria Screen - G0231
- ICT Diagnostics Malaria Dual - ML03
- ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
- Malaria Pan Test - MAL-W23N-001
- One Step Malaria P.f/Pan Test - W56-C
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- NanoSign Malaria Pf/Pv Ag - RMAD10
- OptiMAL-IT - 710024
- SD BIOLINE Malaria Ag - 05FK40

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

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.

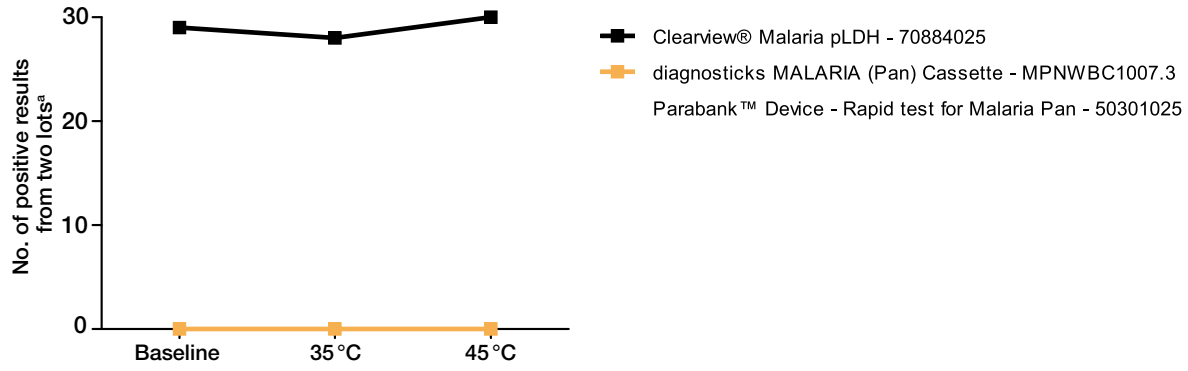


ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test - ITP11003 TC40
Advantage Malaria Card - IR211025
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit - RG19-12
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
CareStart™ Malaria pLDH 3 Line Test - G0121
CareStart™ Malaria Screen - G0231
Clearview® Malaria Combo - VB11
Clearview® Malaria Dual Test Device - VB20
Core™ Malaria Pv/Pf - MAL-190022
diagnosticks MALARIA (Pan/Pf) Cassette - MPNFWBC1007.4
diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
ICT Diagnostics Malaria Dual - ML03
IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
One Step Malaria P.f/Pan Test - W56-C
OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
OnSite Pf/Pan Malaria Ag Rapid Test - R0113C
Parascreen™ Device - Rapid test for Malaria Pan/Pf - 50310025
SD BIOLINE Malaria Ag P.f/Pan - 05FK60
Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMT-T402
Core™ Malaria Pan/Pv/Pf - MAL-190026
ICT Diagnostics Malaria Combo - ML02
Malaria Pan Test - MAL-W23N-001
NanoSign Malaria Pf/Pan Ag - RMAP10
SD BIOLINE Malaria Ag - 05FK40
OptiMAL-IT - 710024
Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
NanoSign Malaria Pf/Pv Ag - RMAD10

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

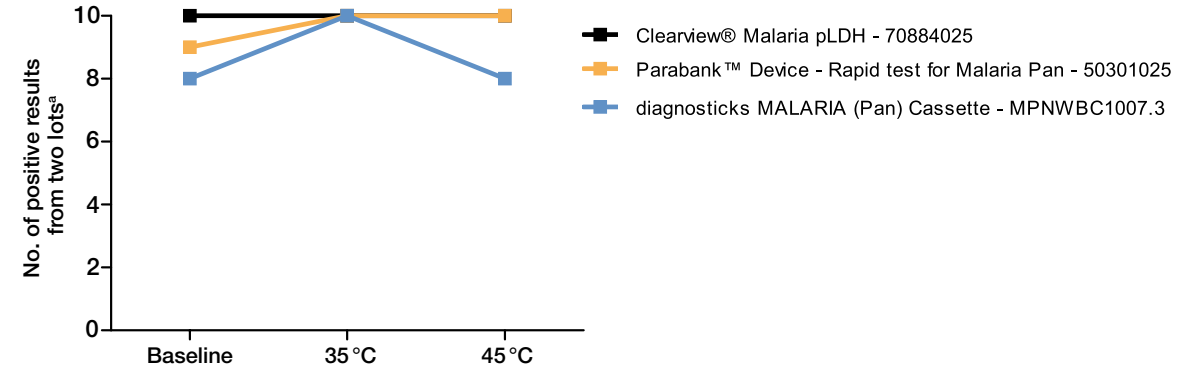
12.2. Pan-specific test lines

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.



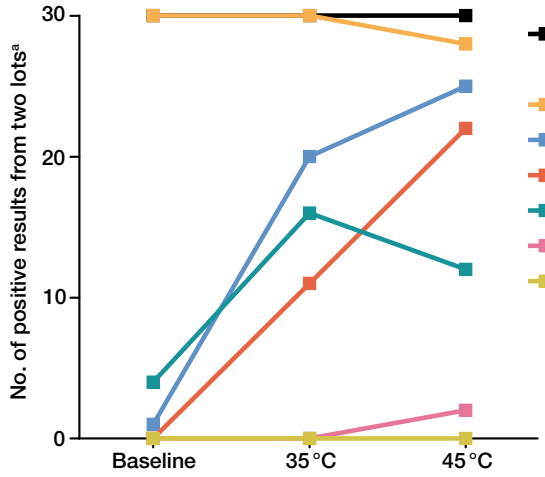
[a] Maximum score is 30 (15 tests x 2 lots)

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)

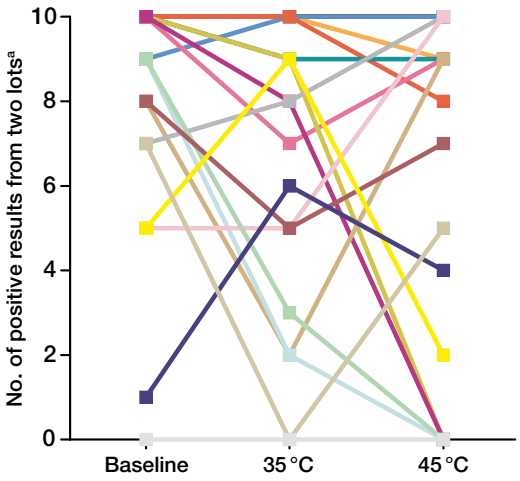
Figure 22: Heat stability of pan-line of combination tests against a low density *P. falciparum* sample (200 parasites/µl). Positivity rate at baseline, and after 60 days incubation.



CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
CareStart™ Malaria pLDH 3 Line Test - G0121
CareStart™ Malaria Screen - G0231
OnSite Pf/Pan Malaria Ag Rapid Test - R0113C
One Step Malaria P.f/Pan Test - W56-C
Malaria Pan Test - MAL-W23N-001
Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
Clearview® Malaria Combo - VB11
Clearview® Malaria Dual Test Device - VB20
Core™ Malaria Pan/Pv/Pf - MAL-190026
diagnosticks MALARIA (Pan/Pf) Cassette - MPNFWBC1007.4
diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
ICT Diagnostics Malaria Combo - ML02
ICT Diagnostics Malaria Dual - ML03
IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
NanoSign Malaria Pf/Pan Ag - RMAP10
NanoSign Malaria Pf/Pv Ag - RMAD10
OptiMAL-IT - 710024
Parascreen™ Device - Rapid test for Malaria Pan/Pf - 50310025
SD BIOLINE Malaria Ag - 05FK40
SD BIOLINE Malaria Ag P.f/Pan - 05FK60
Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMT-T402

[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.



- CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
- CareStart™ Malaria pLDH 3 Line Test - G0121
- CareStart™ Malaria Screen - G0231
- Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
- BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
- Parascreen™ Device - Rapid test for Malaria Pan/Pf - 50310025
- OnSite Pf/Pan Malaria Ag Rapid Test - R0113C
- diagnosticks MALARIA (Pan/Pf) Cassette - MPNFWBC1007.4
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60
- OptiMAL-IT - 710024
- ICT Diagnostics Malaria Dual - ML03
- SD BIOLINE Malaria Ag - 05FK40
- One Step Malaria P.f/Pan Test - W56-C
- Clearview® Malaria Combo - VB11
- IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
- ICT Diagnostics Malaria Combo - ML02
- Core™ Malaria Pan/Pv/Pf - MAL-190026
- Clearview® Malaria Dual Test Device - VB20
- Malaria Pan Test - MAL-W23N-001
- diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
- ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
- NanoSign Malaria Pf/Pan Ag - RMAP10
- NanoSign Malaria Pf/Pv Ag - RMAD10
- Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMT-T402

[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. It is strongly recommended that ease-of-use and screening for major test anomalies also be assessed during product selection processes when procuring RDTs (Annex 5b).

Table 6: Ease of use description of malaria RDTs included in Round 3: WHO Malaria RDT Product Testing

Product	Catalogue number	Manufacturer	Blood safety[a]				Instruction quality[b]				Combined score (max. 5)	Number of timed steps	Total time to result	Blood transfer device	Language of instruction	Items included in package[c]
			Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result	Diagram of result & method	Score (max. 2)						
Pf only																
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (non color change)
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	1	N/A	1	2		1	1	2	4	1	20	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Desiccant (Non-Color Change)
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	1	N/A	1	2		1	1	2	4	1	15	Pipette	English, French, Portuguese, Spanish	Cassette, Transfer Pipette, Buffer, Desiccant (color-Change)
Core™ Malaria Pf	MAL-190020	Core Diagnostics	1	0	1	2		1	0	1	3	1	20	loop	English	Cassette, Transfer Loop, Buffer, Alcohol Swabs, Lancets, Desiccant (Color-Changing)
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (Color-Changing)
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	1	N/A	1	2		1	1	2	4	1	20	N/A	English	Cassette, Buffer, Desiccant (Non-Color Change)
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	1	0	1	2		1	1	2	4	1	15	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Lancet, Desiccant (non Color Change)
One Step Malaria P.F Test (cassette)[d]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1	N/A	1	2	N/A	N/A	N/A	N/A	N/A	1	15	N/A	na	Cassette, Buffer, Desiccant (Non-Color Change)
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	1	1	1	3		1	1	2	5	1	15	Pipette	English	Cassette, Transfer Pipettes, Lancet (retractable Needle), Alcohol Swab, Buffer, Desiccant (color-change)
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0	N/A	1	1		1	1	2	3	1	30	Pipette	English	Cassette, Transfer Pipettes, Buffer, Desiccant (Non-Color Change)
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria (Ver. 3)	30301025	Orchid Biomedical Systems	1	0	1	2		1	0	1	3	1	20	loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (Non-Color Change)
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria (Ver. 3)	30302025	Orchid Biomedical Systems	1	0	0	1		1	0	1	2	1	20	loop	English	Dipstick, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (Non-Color Change)
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	1	0	1	2		1	1	2	4	1	30	Capillary tube	English	Cassette, Capillary Tubes, Lancet, Alcohol Swabs, Buffer, Desiccant (Non-Color-Change)
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	1	0	0	1		1	1	2	3	1	30	Capillary tube	English	Dipstick, Capillary Tubes, Lancet, Alcohol Swabs, Buffer, Desiccant (Non-Color-Change)
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[f]	05FK90	Standard Diagnostics Inc.	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer Desiccant (Non Color Change)
Pf and Pan																
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer Desiccant (Non Color Change)
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	1	N/A	1	2		1	1	2	4	1	20	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Desiccant (Non-Color Change)
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, Inc.	1	0	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Transfer Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (non color Change)
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, Inc.	1	0	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Transfer Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (non color Change)
CareStart™ Malaria Screen	GO231	Access Bio, Inc.	1	0	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Transfer Pipette, Buffer, Alc. Swabs, Lancets, Desiccant (non color Change)
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	1	N/A	1	2		1	1	2	4	1	15	Pipette	English, French, Portugese, Spanish	Cassette, Transfer Pipette, Buffer, Desiccant (color-Change)

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	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)						
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	1	N/A	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (color-Change)
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swap, Buffer, Desiccant(Non-color Change)
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (Color-Changing)
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	1	N/A	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (Color-Changing)
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	1	N/A	1	2		1	1	2	4	1	20	N/A	English	Cassette, Buffer, Desiccant (Non-Color Change)
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Buffer, Transfer Pipette, Desiccant (Non-Color Change)
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	1	N/A	1	2		1	1	2	4	1	20	N/A	English	Cassette, Buffer, Desiccant (Non color change)
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	1	N/A	1	2		1	1	2	4	1	20	N/A	English	Cassette, Buffer, Desiccant (Non color change)
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (color-change)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	1	0	1	2		1	1	2	4	1	15	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Lancet, Desiccant (non Color Change)
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd	1	0	1	2		1	1	2	4	1	15	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Lancet, Desiccant (non Color Change)
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	1	1	1	3		1	1	2	5	1	15	Pipette	English	Cassette, Transfer Pipettes, Lancet (retractable Needle), Alcohol Swab, Buffer, Desiccant (color-change)
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0	N/A	1	1		1	1	2	3	1	30	Pipette	English	Cassette, Transfer Pipettes, Buffer, Desiccant (Non-Color Change)
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0	0	1	1		1	0	1	2	4	20	Capillary tube	English, French, Portuguese, Spanish ,German, Italian	Cassette, Capillary Tubes, Buffer, Alcohol Swabs, Lancet, Desiccant (Non-Color Change), Cover
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (color-change)
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	1	0	1	2		1	1	2	4	1	15	Capillary tube	English, French, Portuguese, Spanish	Cassette, Capillary Tubes, Alcohol Swabs, Lancets, Buffer, Desiccant (Non-Color Change)
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	1	0	1	2		1	1	2	4	1	15	Capillary tube	English, French, Portuguese, Spanish	Cassette, Capillary Tubes, Alcohol Swabs, Lancets, Buffer, Desiccant (Non-Color Change)
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	1	N/A	1	2		1	1	2	4	2	15	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (non color change)
Pf and Pv																
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	1	N/A	1	2		1	1	2	4	1	15	Pipette	English	Cassette, Transfer Pipette, Buffer, Desiccant (non color change)
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	1	0	1	2		1	1	2	4	1	20	Loop	English	Cassette, Transfer Loop, Buffer, Lancet, Alcohol Swab, Desiccant (Non-color Change)

Table 6 (continued)

Product	Catalogue number	Manufacturer	Blood safety[a]				Instruction quality[b]				Combined score (max. 5)	Number of timed steps	Total time to result	Blood transfer device	Language of instruction	Items included in package[c]
			Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result	Diagram of result & method	Score (max. 2)						
BIONOTE MALARIA P.f.&t P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	1	N/A	1	2		1	1	2	4	1	20	Capillary tube	English	Cassette, Capillary Tubes, Buffer, Desiccant (Non-Color Change)
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Buffer, Alcohol Swabs, Lancets, Desiccant (Color-Changing)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	1	N/A	1	2		1	1	2	4	1	20	N/A	English	Cassette, Buffer, Desiccant (Non color change)
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	N/A	1	1		1	1	2	3	1	30	Pipette	English	Cassette, Transfer Pipettes, Buffer, Desiccant (Non-Color Change)
Pf, Pan and Pv																
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Buffer, Alcohol Swabs, Lancets, Desiccant (Color-Changing)
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swap, Buffer, Desiccant(Non-color Change)
Pan only																
Clearview® Malaria pLDH	70884025	Orgenics Ltd.	1	N/A	1	2		1	1	2	4	1	20	Pipette	English	Cassette, Buffer, Transfer Pipette, Desiccant (Non-color Change)
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swap, Buffer, Desiccant(Non-color Change)
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	1	0	1	2		1	0	1	3	1	20	Loop	English	Cassette, Transfer Loop, Lancet, Alcohol Swab, Buffer, Desiccant (color-change)

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

N/A - not applicable

[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 shouls 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 correct 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 3 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 23 re-submitted products rose from 61.3% to 74.7% and 63.1% to 83.8%, respectively for *P. falciparum* detection. For *P. vivax*, the mean and median rose from 31.1% to 60.7% and from 30.0% to 62.9%, respectively. The results for re-submitted products in Round 3 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 mean PDS for Round 3 was higher than previous rounds while, importantly, the mean false positive rate rose from 3.5% and 4.3% in Rounds 1 and 2, respectively, to 5.9%; however, the median fell from 1.8% and 2.0% (Rounds 1 and 2) to 1.0% in Round 3. Overall, this indicates an improvement in test quality 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 aim to detect, e.g. *P. falciparum* only, *P. falciparum* and non-*falciparum* species, non-*P. falciparum species only,* or all malaria species without discrimination. 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[22]. 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).[23] 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 *(5)*.

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

[22] Information note on interim selection criteria for procurement of malaria rapid diagnostic tests (RDTs) (January 2010) *http://new.paho.org/hq/dmdocuments/2010/infoRDTinterimcriteria.pdf* (accessed 25 September, 2011)

[23] In the report of WHO Product Testing: Round 1 the PDS was termed the 'Detection Rate'(3).

field, to ensure that expected performance is maintained (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, and 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 *(18, 20)*. 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 significant parasite populations with high frequencies of non-expression of target antigens have been recorded 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.

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.[24]

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.

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

[24] Examples available here: *http://www.wpro.who.int/sites/rdt/using_rdts/training/main.htm* (accessed 25 September, 2011); *http://www.finddiagnostics.org/programs/malaria/find_activities/rdt-job-aids/* (accessed 25 September, 2011)

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.

Several products showed high stability at the temperatures and time periods used in this evaluation. In general, pan-specific lines (pLDH) performed less well at baseline and were less stable than HRP2 test lines, but there was overlap between the stability of tests against these targets with three pLDH test lines on combination tests maintaining very good positivity rates on low parasite densities, after two months at 45°C.

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 *(21, 22)*.

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 *(23)*. 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. 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 *(23-25)*. Annex 5b provides guidance on conducting a field-based ease of use assessment.

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 have current ISO 13485:2003 certification, a standard designed to give assurance of consistency of quality of 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 (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[25] 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, and the development of panels based on recombinant antigens is a focus of work by FIND, TDR and WHO.

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

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 stability of tests targeting these different antigens also overlapped.

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 (*18,20*). 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 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)*.

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.

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.[26]

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

[26] An interactive guide designed to help short-list test according to individual programme needs, based on the performance of tests in rounds 1, 2 and 3 of the WHO Product Testing Programme can be found at *http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/*

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, 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.

15.2. Lot testing

Complementary to the product testing programme, WHO, TDR 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 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 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 at intervals until their expiry date. Initial results are available after five days and then sent at regular intervals. Details of the protocol can be found in the published methods manual for lot testing *(17)*. 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*

16. CONCLUSIONS

This study adds to the large data set on malaria RDT performance published in 2009 and 2010 after the first and second rounds of evaluations *(3, 4)*. The product testing programme is a landmark in the field of malaria RDT evaluations in terms of the number of products evaluated and its comprehensiveness. New laboratory methods were 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 Round 1 and Round 2 results impacted on the procurement practices of countries and procurement agencies, and this Report of Round 3 will add considerably to the number of well-performing RDTs for which comprehensive performance data is now available, and provides updated data on products that have been re-submitted following product modification.

17. REFERENCES

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ANNEXES

Annex 1: Characteristics of rapid malaria tests in Round 3

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 volume (drops)	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 Pan/P.f. Rapid Test Device (Whole Blood)	IMA-B402	F,P	aldolase, HRP2	√	aldolase	HRP2		10	4	15	20	C	A
Access Bio, INC.	CareStart ™Malaria pLDH 3 Line Test	G0121	F,P	pan-pLDH, pf-pLDH	√	Pan pLDH	Pf-pLDH		5	2	20		C	A
	CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	F,P	pan-pLDH, HRP2	√	HCG	pan-pLDH	HRP2	5	2	20		C[f]	A
	CareStart™ Malaria Screen	G0231	F,P	pan-pLDH, HRP2, pf-pLDH	√	Pan pLDH	HRP2/Pf-pLDH		5	2	20		C	A
ACON Biotech (Hangzhou) Co. Ltd	Surestep™ Malaria Pf/Pan Rapid Test Device (Whole Blood)	IMA-T402	F,P	aldolase, HRP2	√	aldolase	HRP2		10	multi-step	15	20	C	A
AZOG, Inc.	Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	F,P	pan-pLDH, pf-pLDH	√	pan-pLDH	pf-pLDH		5	2	20	20	C	A
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	F,V	pv-pLDH, HRP2	√	pv-pLDH	HRP2		5	2	20	20	E	A
	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	2	20	20	C	A
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10	F	HRP2	√	HRP2			5	4	15	20	A	A
	NanoSign Malaria Pf/Pan Ag	RMAP10	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	4	15	20	C	A
	NanoSign Malaria Pf/Pv Ag	RMAD10	F,P	pan-pLDH, pf-pLDH	√	pan-pLDH	pf-pLDH		5	4	15	20	C	A
BioNote,Inc.	BIONOTE MALARIA P.f&P.v Ag Rapid Test Kit	RG19-12	F,V	pv-pLDH, HRP2	√	pv-pLDH	HRP2		5	4	20	30	E	A
	BIONOTE MALARIA P.f&Pan Ag Rapid Test Kit	RG19-08	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	4	20	30	C	A
	BIONOTE MALARIA P.f Ag Rapid Test Kit	RG19-11	F	HRP2	√	HRP2			5	4	20	30	A	A
Biosynex	IMMUNOQUICK CONTACT falciparum	0519K25	F	HRP2	√	HRP2			15	4	20	20	A	A
	IMMUNOQUICK CONTACT MALARIA +4	0525K25	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		15	4	20	20	C	A
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (cassette)	522352	F	HRP2	√	HRP2			5	5	15	20	A	A
Core Diagnostics	Core™ Malaria Pf	MAL-190020	F	HRP2	√	HRP2			5	2	20		A	A
	Core™ Malaria Pv/Pf	Mal-190022	F,V	pv-pLDH, HRP2	√	pv-pLDH	HRP2		5	2	20		E	A
	Core™ Malaria Pan/Pv/Pf	Mal-190026	F,P,V	pan-pLDH, pv-pLDH, HRP2	√	pan-pLDH	pv-pLDH	HRP2	5	2	20		G	A
CTK Biotech, Inc.	OnSite Pf Ag Rapid Test	R0114C	F	HRP2	√	HRP2			5	3	30		A	A
	OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	F,P	pan-pLDH, HRP2	√	HRP2	pan-pLDH		5	3	30		D	A
	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	F,V	pv-pLDH, HRP2	√	HRP2	pv-pLDH		5	3	30		F	A
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024	F,P	pan-pLDH, pf-pLDH	√	pan-pLDH	pf-pLDH		10	multi-step			C	A
Dima • Gesellschaft für Diagnostika mbH	Malaria Pan test	MAL-W23N-001	F,P	aldolase, HRP2	√	HRP2	aldolase		5	4	15	30	D	A
R & R Marketing / ICT Diagnostics	ICT Diagnostics Malaria Combo	ML02	F,P	aldolase, HRP2	√	HRP2	aldolase		5	5	15		D	A
	ICT Diagnostics Malaria Dual	ML03	F,P	pan-pLDH, HRP2	√	HRP2	pan-pLDH		5	5	20		D	A
	ICT Diagnostics Malaria P.f	ML01	F	HRP2	√	HRP2			5	5	15		A	A
InTec Products, Inc.	Advanced Quality™ One Step Malaria P.f/P.v Tri-line Test	ITP11003 TC40	F,V	pv-pLDH, HRP2	√	pv-pLDH	HRP2		10	3	15		E	A
	Advanced Quality™ One Step Malaria P.f Test	ITP11002 TC40	F	HRP2	√	HRP2			10	3	15		A	A
J. Mitra & Co. Pvt. Ltd.c/o Biomed Industries	Advantage Malaria Card	IR211025	F,V	pv-pLDH, HRP2	√	pv-pLDH	HRP2		5	5	20		E	A

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 volume (drops)	Minimum time to results[c] (mins)	Maximum reading time (mins)	Results Interpretation[d] (Type A-J)	Format type[e]
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for P. falciparum Malaria (Ver.3)	30301025	F	HRP2	√	HRP2			5	2	20		A	A
	Paracheck® Pf Dipstick - Rapid test for P. falciparum Malaria (Ver. 3)	30302025	F	HRP2	√	HRP2			5	4 (Test tube)	20		A	D
Orgenics Ltd. (Inverness Medical Innovations)	Clearview® Malaria pLDH	70884025	P	pan-pLDH	√	pan pLDH			5	4	20	60	B	A
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40	F,P	pan-pLDH, pf-pLDH	√	pan-pLDH	pf-pLDH		5	4	15	30	C	A
	SD BIOLINE Malaria Ag P.f/Pan	05FK60	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	4	15	30	C	A
	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	F	pf-pLDH, HRP2	√	pf-pLDH	HRP2		5	4	15	30	J	A
Span Diagnotics Ltd.	ParaHIT® - f (Device)	55IC102-10	F	HRP2	√	HRP2			8	4	30	30	A	A
	ParaHIT® - f (Dipstick)	55IC101-10	F	HRP2	√	HRP2			8	4 (Test tube)	30	30	A	D
SSA Diagnostics & Biotech Systems	diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	P	pan-pLDH	√	pan-pLDH			5	2	20		B	A
	diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	2	20		C	A
	diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	F,P,V	pan-pLDH, pv-pLDH, HRP2	√	pan-pLDH	pv-pLDH	HRP2	5	2	20		G	A
Vision Biotech (Pty) Ltd	Clearview® Malaria Combo	VB11	F,P	aldolase, HRP2	√	HRP2	aldolase		5	5	15		D	A
	Clearview® Malaria Pf	VB01	F	HRP2	√	HRP2			5	5	15		A	A
	Clearview® Malaria Dual Test Device	VB20	F,P	pan-pLDH, HRP2	√	HRP2	pan-pLDH		5	5	20		D	A
Guangzhou Wondfo Biotech Co. Ltd.	One Step Malaria P.f./Pan Whole Blood Test	W56-C	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	4	15	30	C	A
	One Step Malaria P.f Test	W37-C	F	HRP2	√	HRP2			5	4	15	30	A	A
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	F,P	aldolase, HRP2	√	aldolase	HRP2		5	2	20		C	A
	Parabank™ Device - Rapid test for Malaria Pan	50301025	P	pan-pLDH	√	pan-pLDH			5	2	20		B	A
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025	F,P	pan-pLDH, HRP2	√	pan-pLDH	HRP2		5	2	20		C	A

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

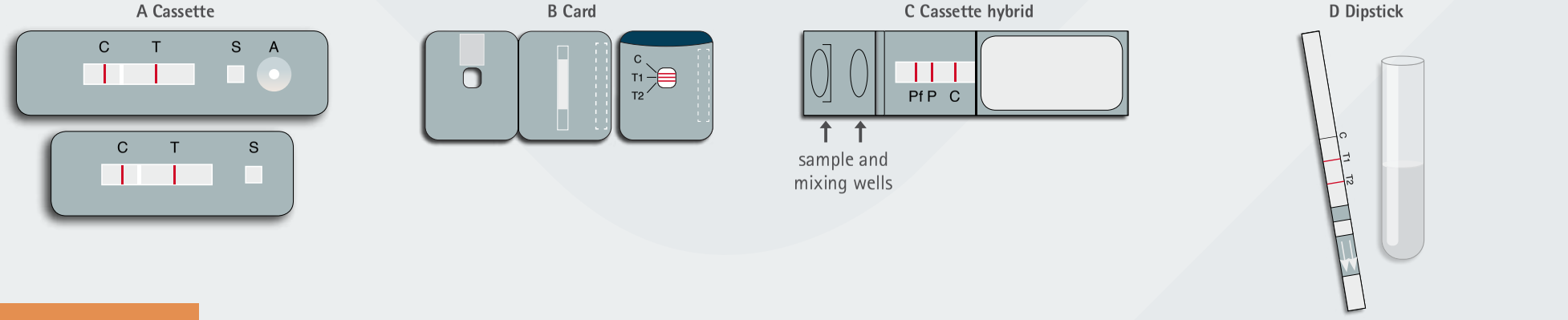
[b] sequence when test held in a horizontal position and the sample well is at the far right and control line, far left

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

[d] See Annex 2

[e] Formats include: cassette (A); card (B); cassette-hybrid (C), dipstick (D); or other. 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.

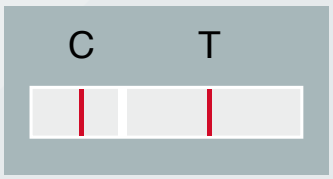
[f] HCG test line not evaluated



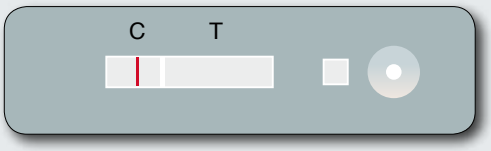
Annex 2: Malaria RDT guide to results interpretation

Type A: Malaria Generic Pf RDT Results Guide

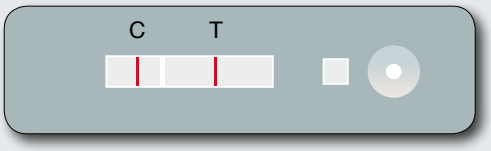
Results Window: C=control line; T=test line with bound HRP-2 or Pf-specific pLDH antibody.



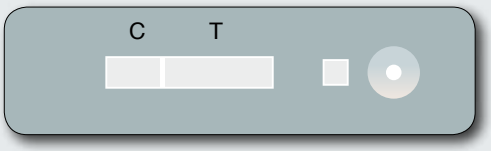
Negative Results: One line 'C' appears in the results window.

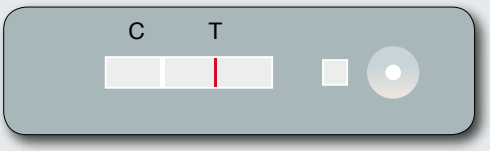


Positive Results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window.
Test is positive even if the test line is faint.



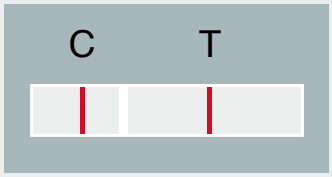
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



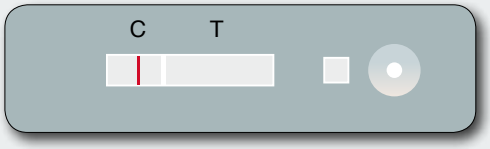


Type B: Malaria Generic Major Plasmodium species (pan) RDT Results Guide

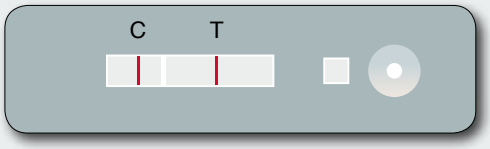
Results Window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



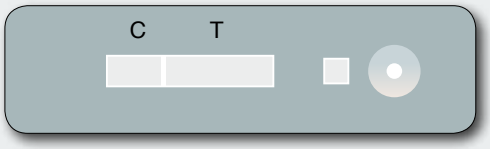
Negative Results: One line 'C' appears in the results window.

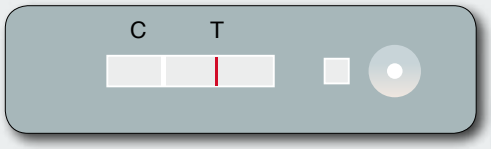


Positive Results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P.malariae*, *P.ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



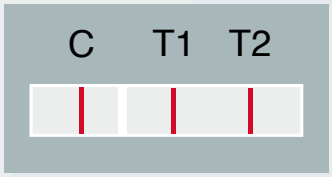
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



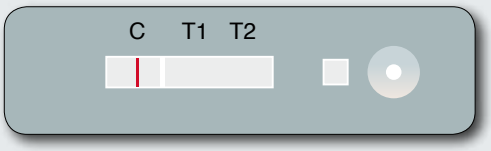


Type C: Malaria Generic Pan-Pf RDT Results Guide

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.

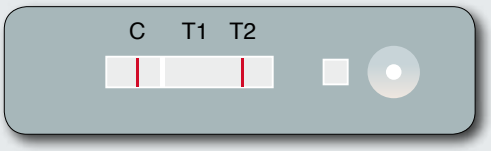


Negative Results: Only one line 'C' appears in the results window.

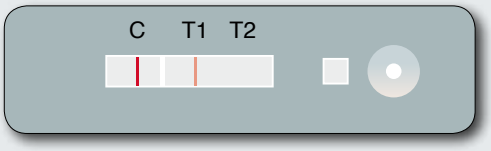


Positive Results:

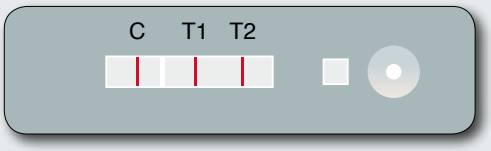
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



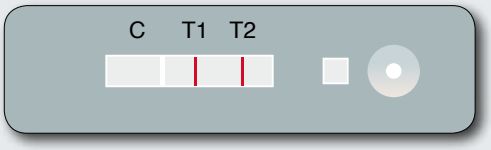
Non-falciparum infection (*P. vivax, P.ovale, P.malariae*) or mixed infection of these:
Two lines 'C' and 'T1" appear in the results window.

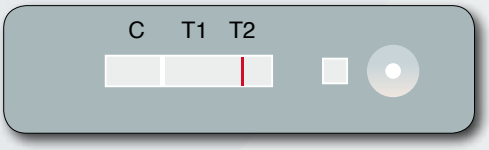


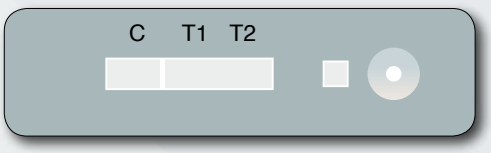
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

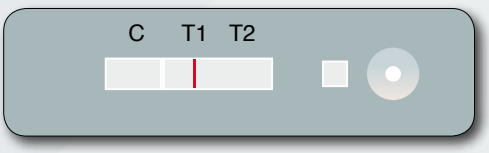


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



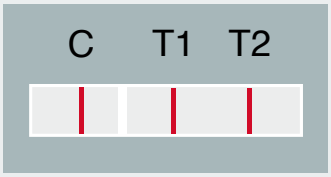




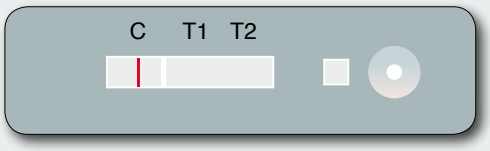


Type D: Malaria Generic Pf-Pan RDT Results Guide

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.

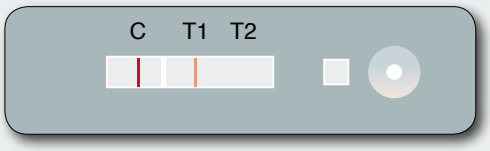


Negative Results: Only one line 'C' appears in the results window.

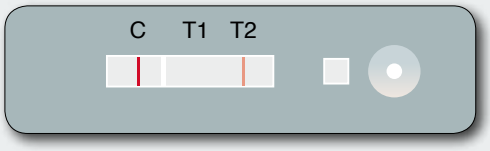


Positive Results:

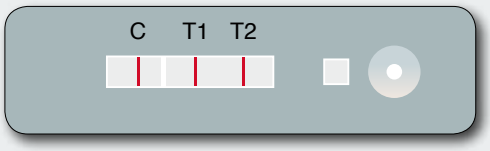
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



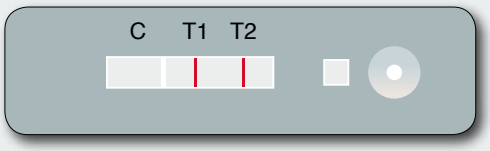
Non-falciparum infection (*P. vivax*, *P.ovale*, *P.malariae*) or mixed infection of these. Two lines 'C' and 'T2' appear in the results window.

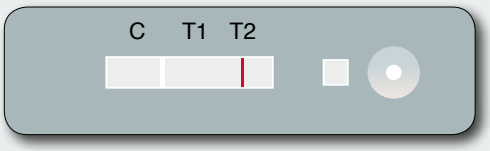


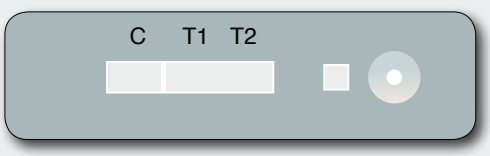
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

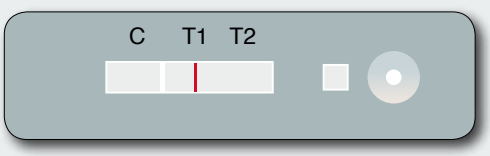


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



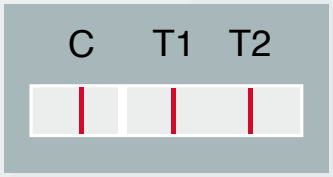




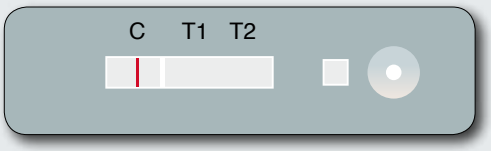


Type E: Malaria Generic Pv-Pf RDT Results Guide

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.

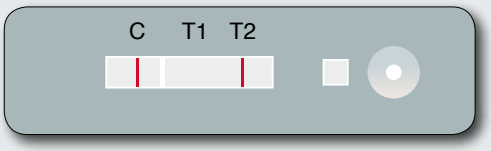


Negative Results: Only one line 'C' appears in the results window.

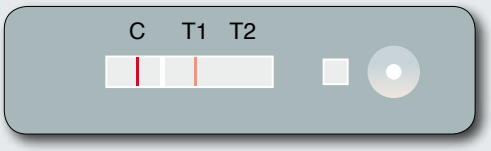


Positive Results:

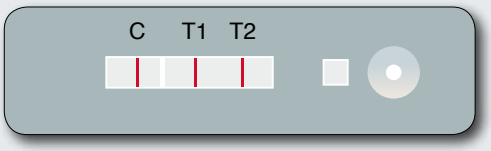
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



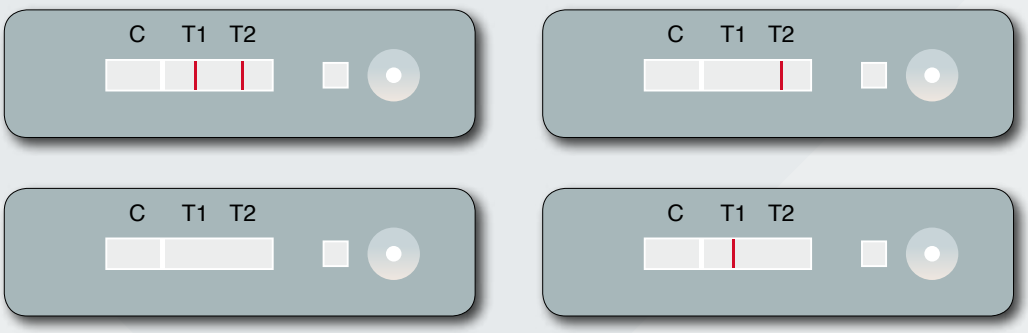
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



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

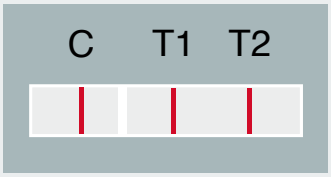


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

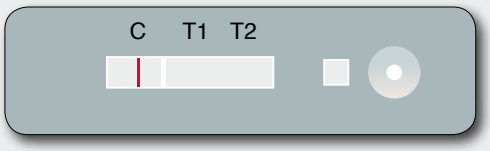


Type F: Malaria Generic Pf-Pv RDT Results Guide

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.

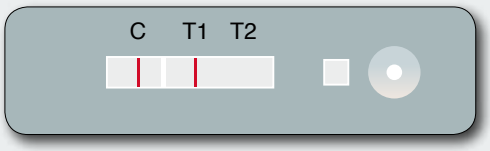


Negative Results: Only one line 'C' appears in the results window.

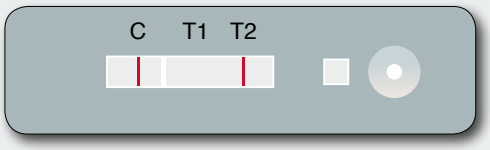


Positive Results:

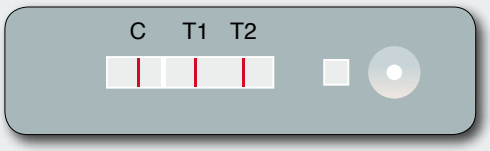
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



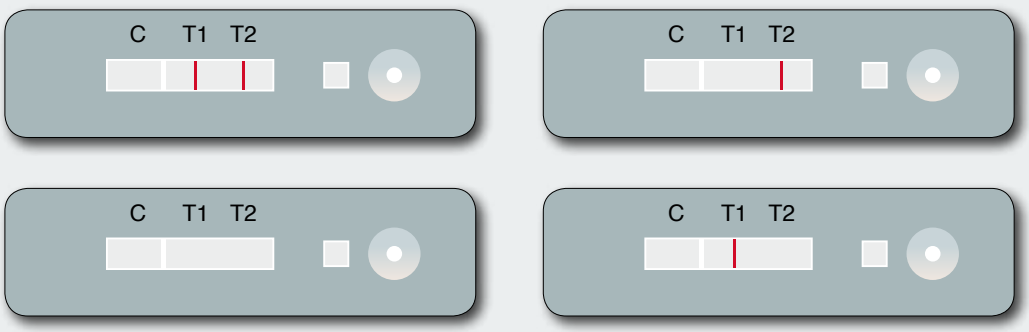
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



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

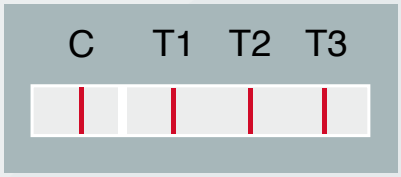


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

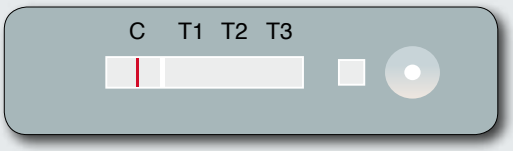


Type G: Malaria Generic Pan-Pv-Pf RDT Results Guide

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

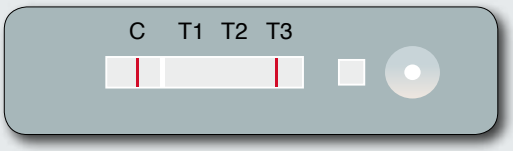


Negative Results: Only one line 'C' appears in the results window.

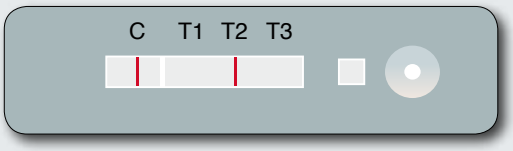


Positive Results:

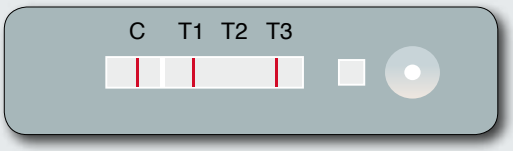
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



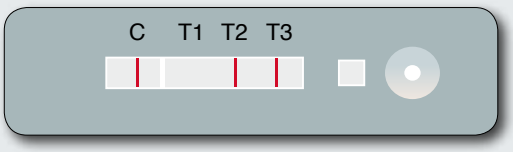
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



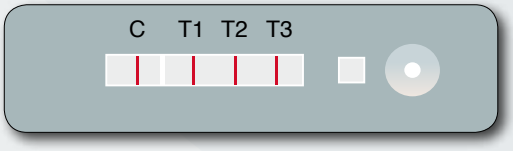
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



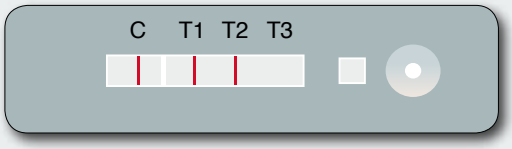
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



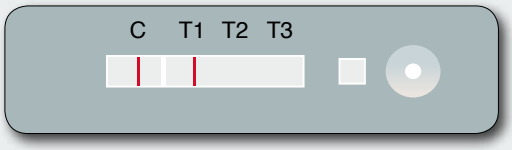
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



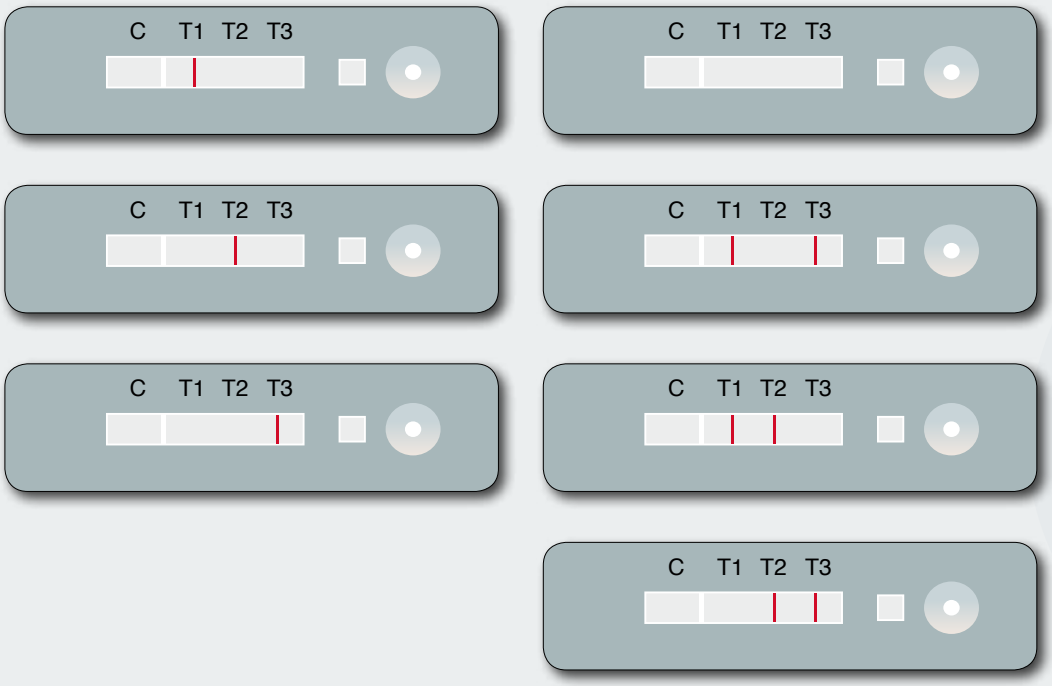
P. vivax with or without *P. ovale* and/or *P. malariae* infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



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

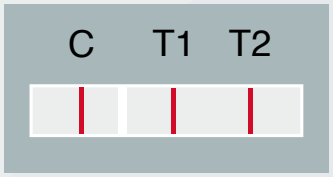


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.

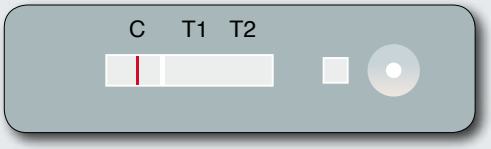


Type H: Malaria Generic VOM[1]-Pf RDT Results Guide

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

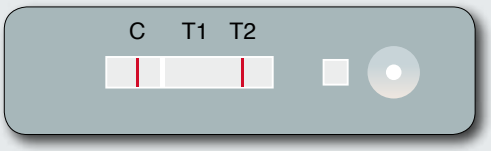


Negative Results: Only one line 'C' appears in the results window.

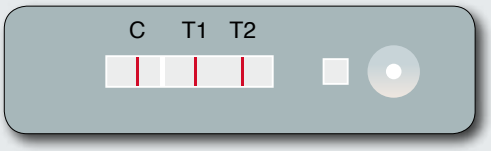


Positive Results:

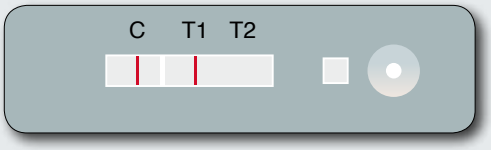
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



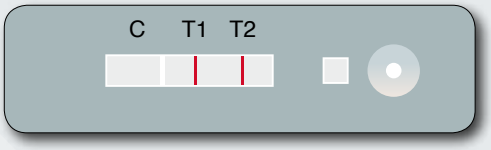
P. falciparum mixed infection (with anyone or more of *P. vivax*, *P. ovale* and *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

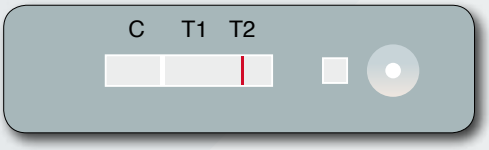


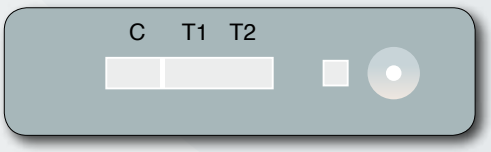
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection of these. Two lines 'C' and 'T1' appear in the results window.

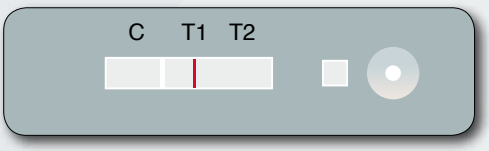


Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.





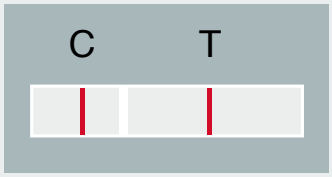




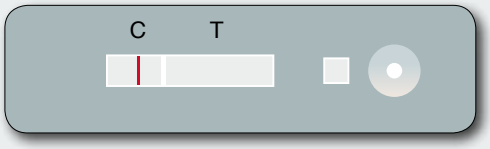
[1] VOM -*P. vivax, P. ovale, P. malariae*

Type I: Malaria Generic Pv RDT Results Guide

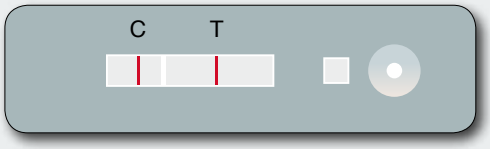
Results Window: C=control line; T=test line bound with *P. vivax* specific pLDH.



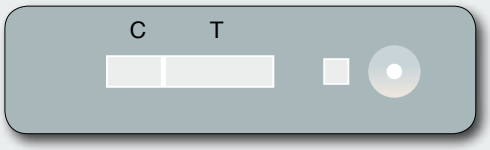
Negative Results: Only one line 'C' appears in the results window.

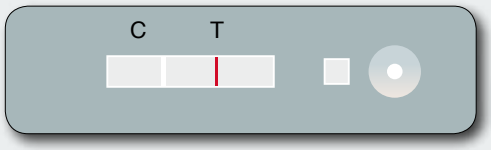


Positive Results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



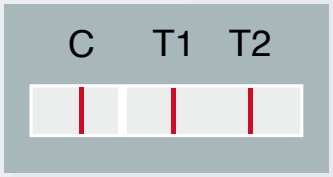
Invalid Results: No 'C' line appears in the results window. Repeat the test using a new RDT if no control line appears.



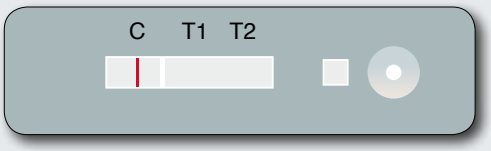


Type J: Malaria Generic Pf-Pf RDT Results Guide

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

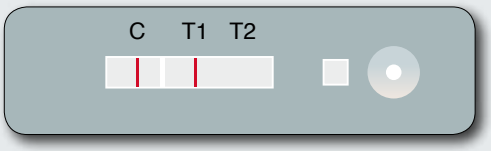


Negative Results: Only one line 'C' appears in the results window.

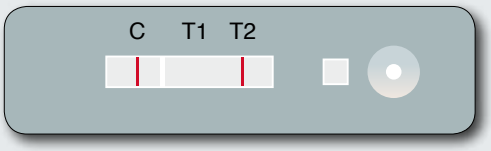


Positive Results:

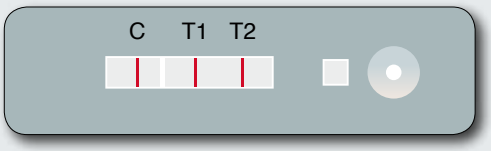
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



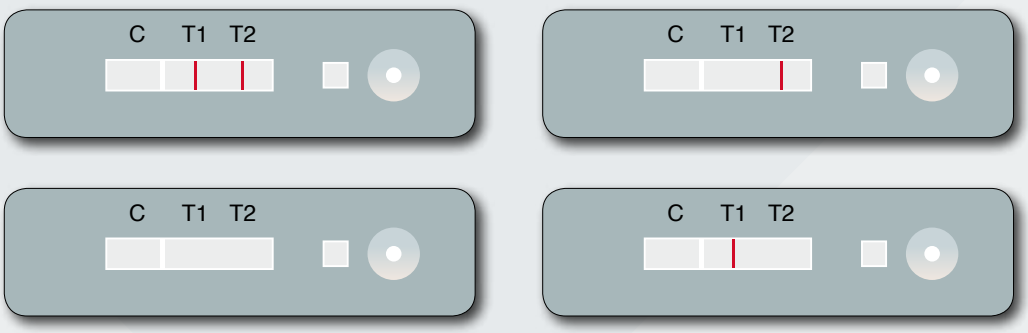
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



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.



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										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	19.0	18.0	18.0	19.0	18.0 (19)	18.0 (19)	20.0	20.0
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	20.0	19.0	19.0	19.0	19.0	19.0	20.0	20.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	20.0	19.0 (19)	19.0 (19)	20.0	20.0	20.0	20.0	20.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	19.0	19.0	19.0	19.0	19.0	19.0	20.0	20.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	19.0	19.0	19.0	16.0	16.0	16.0	20.0	20.0
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	18.0	18.0	17.0	17.0 (19)	19.0	17.0 (19)	19.0 (19)	19.0 (19)
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	19.0	18.0	18.0	17.0 (19)	18.0	17.0 (19)	19.0	19.0
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	16.0	16.0	14.0	18.0	16.0	16.0	20.0	20.0
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	19.0	19.0	18.0	20.0	19.0	19.0	20.0	20.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	19.0	20.0	19.0	20.0	19.0 (19)	19.0 (19)	20.0	20.0
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	19.0	19.0	18.0	18.0	18.0	17.0	20.0	20.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	16.0	17.0	16.0	17.0	17.0	17.0	20.0	20.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
Pf and Pan										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	16.0	15.0	15.0	16.0	16.0	15.0	20.0	18.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	20.0	19.0	19.0	19.0	18.0	18.0	20.0	20.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	20.0	18.0	18.0	20.0	20.0	20.0	20.0	20.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	17.0	17.0	17.0	17.0	18.0	16.0	20.0	20.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	17.0 (19)	18.0	17.0 (19)	18.0	18.0	18.0	20.0	19.0 (19)
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	18.0	18.0	17.0	18.0	19.0	18.0	20.0	20.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	19.0	18.0	18.0	20.0	17.0	17.0	20.0	19.0 (19)
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	18.0	16.0 (19)	16.0 (19)	17.0	19.0	17.0	20.0	20.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	15.0	19.0	15.0	17.0	14.0	14.0	20.0	20.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	1.0	1.0	0.0	1.0	0.0	0.0	18.0	19.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	19.0 (19)	19.0 (19)	18.0 (18)	19.0	18.0 (18)	17.0 (18)	18.0 (18)	18.0 (18)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	19.0	19.0	19.0	19.0	18.0	18.0	20.0	20.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	19.0	17.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	8.0	9.0	6.0	11.0 (19)	11.0	9.0 (19)	19.0 (19)	20.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	19.0	19.0	18.0	20.0	20.0	20.0	20.0	20.0

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
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	15.0	15.0	13.0	12.0	13.0	9.0	20.0	20.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	1.0	1.0	0.0	1.0	1.0	0.0	20.0	20.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	19.0	19.0	19.0	19.0	19.0	19.0	20.0	20.0
Pf and Pv										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	18.0	18.0	17.0	19.0	17.0	17.0	20.0	20.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	20.0	18.0 (19)	18.0 (19)	19.0	20.0	19.0	20.0	20.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	20.0	19.0 (19)	19.0 (19)	20.0	20.0	20.0	20.0	20.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	20.0	19.0	19.0	19.0	19.0	18.0	20.0	20.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	20.0	20.0	20.0	17.0	19.0	16.0	20.0	20.0
Pf, Pan and Pv										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	20.0	20.0	20.0	20.0	20.0	20.0	19.0	20.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	19.0 (19)	20.0	19.0 (19)	20.0	20.0	20.0	20.0	20.0
Pan only										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	18.0	19.0	18.0	19.0	19.0	19.0	20.0	20.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	5.0	9.0	4.0	2.0	5.0	2.0	20.0	20.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	8.0	5.0	3.0	6.0	6.0	4.0	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.

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																						
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	1.3	13.8	73.8	11.3	0.0	0.0	0.0	10.0	50.0	40.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	7.5	10.0	51.3	22.5	8.8	0.0	0.0	2.5	12.5	85.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	3.8	15.0	42.5	30.0	8.8	0.0	0.0	2.5	12.5	85.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	0.0	3.8	27.5	42.5	26.3	0.0	0.0	0.0	10.0	90.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	5.0	20.0	28.8	35.0	11.3	0.0	0.0	2.5	10.0	87.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	12.5	23.8	45.0	18.8	0.0	0.0	0.0	7.5	27.5	65.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	10.0	12.5	63.8	11.3	2.5	5.0	2.5	7.5	27.5	57.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	10.0	11.3	36.3	33.8	8.8	5.0	0.0	2.5	12.5	80.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	17.5	48.8	22.5	10.0	1.3	0.0	2.5	7.5	32.5	57.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	3.8	8.8	65.0	22.5	0.0	0.0	0.0	10.0	42.5	47.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	2.5	8.8	21.3	45.0	22.5	0.0	0.0	2.5	2.5	95.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	0.0	12.5	43.8	33.8	10.0	0.0	0.0	2.5	25.0	72.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	7.5	10.0	57.5	22.5	2.5	0.0	0.0	7.5	15.0	77.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	16.3	10.0	61.3	12.5	0.0	0.0	0.0	15.0	20.0	65.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[c]	05FK90	Standard Diagnostics Inc.	1.3/93.8	13.8/6.3	18.8/0.0	40.0/0.0	26.3/0.0	0.0/0.0	0.0/20.0	0.0/62.5	7.5/17.5	92.5/0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan																						
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	21.3	21.3	47.5	8.8	1.3	5.0	0.0	12.5	27.5	55.0	100.0	0.0	0.0	0.0	0.0	77.5	22.5	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	1.3	10.0	25.0	47.5	16.3	0.0	0.0	0.0	12.5	87.5	92.5	7.5	0.0	0.0	0.0	0.0	5.0	95.0	0.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	5.0	18.8	30.0	35.0	11.3	0.0	0.0	0.0	12.5	87.5	0.0	27.5	52.5	18.8	1.3	0.0	0.0	0.0	7.5	92.5
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	2.5	16.3	18.8	40.0	22.5	0.0	0.0	0.0	5.0	95.0	1.3	20.0	43.8	23.8	11.3	0.0	0.0	0.0	2.5	97.5
CareStart™ Malaria Screen	GO231	Access Bio, INC.	1.3	20.0	23.8	37.5	17.5	0.0	0.0	0.0	5.0	95.0	0.0	22.5	48.8	23.8	5.0	0.0	0.0	0.0	2.5	97.5
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	13.8	23.8	31.3	17.5	13.8	0.0	0.0	2.5	12.5	85.0	97.5	2.5	0.0	0.0	0.0	2.5	62.5	32.5	2.5	0.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	11.3	22.5	33.8	21.3	11.3	2.5	0.0	7.5	12.5	77.5	91.3	8.8	0.0	0.0	0.0	17.5	32.5	50.0	0.0	0.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.0	2.5	28.8	41.3	27.5	0.0	0.0	2.5	5.0	92.5	88.8	11.3	0.0	0.0	0.0	5.0	17.5	72.5	5.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	8.8	22.5	27.5	28.8	12.5	0.0	0.0	2.5	10.0	87.5	98.8	1.3	0.0	0.0	0.0	2.5	62.5	30.0	5.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	7.5	20.0	37.5	28.8	6.3	2.5	0.0	5.0	25.0	67.5	73.8	26.3	0.0	0.0	0.0	5.0	20.0	72.5	2.5	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	12.5	25.0	43.8	15.0	3.8	0.0	0.0	7.5	30.0	62.5	92.5	7.5	0.0	0.0	0.0	0.0	12.5	82.5	5.0	0.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	18.8	47.5	17.5	15.0	1.3	0.0	0.0	17.5	20.0	62.5	86.3	12.5	1.3	0.0	0.0	52.5	47.5	0.0	0.0	0.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	0.0	12.5	15.0	51.3	21.3	0.0	0.0	0.0	10.0	90.0	100.0	0.0	0.0	0.0	0.0	67.5	30.0	2.5	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	96.3	3.8	0.0	0.0	0.0	7.5	85.0	7.5	0.0	0.0	92.5	7.5	0.0	0.0	0.0	45.0	55.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	1.3	6.3	45.0	37.5	10.0	0.0	0.0	2.5	5.0	92.5	70.0	30.0	0.0	0.0	0.0	10.0	2.5	80.0	7.5	0.0
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	6.3	18.8	62.5	12.5	0.0	0.0	0.0	10.0	27.5	62.5	100.0	0.0	0.0	0.0	0.0	92.5	7.5	0.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	100.0	0.0	0.0	0.0	0.0	10.0	40.0	50.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	51.3	27.5	18.8	2.5	0.0	2.5	2.5	22.5	20.0	52.5	97.5	2.5	0.0	0.0	0.0	7.5	52.5	37.5	2.5	0.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	2.5	16.3	62.5	17.5	1.3	0.0	0.0	10.0	32.5	57.5	91.3	7.5	1.3	0.0	0.0	5.0	15.0	80.0	0.0	0.0

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
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	31.3	65.0	3.8	0.0	0.0	0.0	0.0	17.5	67.5	15.0	8.8	87.5	3.8	0.0	0.0	0.0	0.0	20.0	65.0	15.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	0.0	1.3	32.5	42.5	23.8	0.0	0.0	0.0	2.5	97.5	77.5	22.5	0.0	0.0	0.0	0.0	7.5	82.5	10.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.0	16.3	13.8	28.8	41.3	0.0	0.0	0.0	5.0	95.0	93.8	6.3	0.0	0.0	0.0	0.0	12.5	67.5	17.5	2.5
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	95.0	5.0	0.0	0.0	0.0	0.0	60.0	37.5	2.5	0.0	97.5	2.5	0.0	0.0	0.0	0.0	75.0	25.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	5.0	7.5	65.0	18.8	3.8	0.0	0.0	5.0	25.0	70.0	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Pf and Pv																						
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	0.0	27.5	53.8	17.5	1.3	0.0	0.0	7.5	40.0	52.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	10.0	11.3	60.0	16.3	2.5	0.0	0.0	7.5	27.5	65.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	3.8	6.3	28.8	46.3	15.0	0.0	0.0	0.0	15.0	85.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	0.0	0.0	31.3	50.0	18.8	0.0	0.0	0.0	12.5	87.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	3.8	26.3	33.8	30.0	6.3	0.0	0.0	5.0	12.5	82.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	5.0	11.3	62.5	17.5	3.8	0.0	0.0	5.0	37.5	57.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf, Pan and Pv																						
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.0	0.0	36.3	43.8	20.0	2.5	0.0	0.0	10.0	87.5	100.0	0.0	0.0	0.0	0.0	17.5	35.0	47.5	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	1.3	3.8	22.5	36.3	36.3	0.0	0.0	0.0	7.5	92.5	97.5	2.5	0.0	0.0	0.0	5.0	50.0	45.0	0.0	0.0
Pan only																						
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	6.3	56.3	37.5	0.0	0.0	0.0	0.0	0.0	57.5	42.5
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	73.8	23.8	2.5	0.0	0.0	0.0	20.0	65.0	15.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	68.8	27.5	3.8	0.0	0.0	0.0	5.0	67.5	27.5	0.0

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

N/A: not applicable

[a] Denotes no band visible

[b] Calculations include invalid tests

[c] Results for pf-HRP2 line/pf-pLDH line, respectively

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=99) Total positive results[a] returned								*P. vivax* samples (n=35) 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=99)	Test 1	Test 2	No. positive agreements[c] (max=99)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=40)	Test 1	Test 2	No. positive agreements[c] (max=40)	Test 1	Test 2
Pf only																		
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	94.0	97.0	94.0	98.0	96.0	95.0	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	93.0	93.0	91.0	86.0.0 (98)	86.0	84.0 (98)	99.0	98.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	90.0	87.0	84.0	91.0	90.0	87.0	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	97.0	96.0	96.0 (98)	97.0	96.0 (98)	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	89.0	88.0	86.0	92.0	92.0	92.0	97.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	85.0	86.0	83.0	87.0	84.0 (98)	83.0 (98)	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	92.0	90.0	88.0	91.0 (98)	91.0	87.0 (98)	98.0 (98)	98.0 (98)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	86.0	81.0 (98)	78.0 (98)	80.0	78.0	73.0	96.0	97.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	75.0	76.0	70.0	72.0	72.0	65.0	97.0 (98)	98.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	89.0	94.0	88.0	96.0	92.0	90.0	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	97.0	95.0 (98)	95.0 (98)	96.0 (98)	96.0	95.0 (98)	95.0 (95)	98.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	94.0	91.0	89.0	93.0	95.0	92.0	98.0	98.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	87.0	88.0	85.0	93.0	89.0	89.0	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	86.0	85.0	83.0	88.0	87.0	83.0	99.0	98.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	97.0	96.0	96.0	93.0	90.0	88.0	99.0	99.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan																		
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	79.0	78.0	75.0	79.0	77.0	74.0	99.0	98.0	0.0	0.0	0.0	0.0	0.0	0.0	24.0	27.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	97.0	95.0	95.0	95.0	95.0	94.0	99.0	98.0	34.0	32.0	32.0	33.0	33.0	32.0	35.0	35.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	95.0	95.0	94.0	87.0	87.0	83.0	99.0	98.0 (98)	35.0	35.0	35.0	35.0	32.0 (34)	32.0 (34)	34.0	35.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	96.0	96.0	96.0	91.0	91.0	88.0	99.0	99.0	35.0	35.0	35.0	34.0	33.0	32.0	35.0	35.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	96.0	94.0	93.0	90.0	91.0	86.0	99.0	99.0	34.0	34.0	33.0	35.0	33.0	33.0	35.0	35.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	85.0	86.0	84.0	93.0	90.0	87.0	99.0	99.0	10.0	9.0	4.0	11.0	11.0	6.0	32.0	34.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	86.0	80.0	78.0	81.0	80.0	74.0	98.0	97.0	27.0 (34)	30.0	25.0 (34)	28.0	28.0	22.0	34.0	34.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	99.0	98.0	98.0	97.0 (98)	97.0 (98)	96.0 (97)	99.0	99.0	31.0	28.0	26.0	29.0	26.0	23.0	34.0 (34)	34.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	90.0	90.0	87.0	93.0	92.0	90.0	98.0	98.0	15.0	14.0	9.0	9.0	12.0	6.0	33.0	33.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	81.0	85.0	79.0	87.0 (98)	87.0 (98)	85.0 (97)	98.0	98.0 (98)	28.0	30.0	25.0	33.0	33.0	31.0	34.0	35.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	80.0	78.0	77.0	79.0 (98)	82.0	77.0 (98)	98.0	98.0	11.0	15.0 (33)	8.0 (33)	15.0	13.0	10.0	33.0	34.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	84.0	82.0	77.0	68.0	66.0	56.0	99.0	96.0	6.0	2.0	1.0	8.0	6.0	1.0	30.0	20.0

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=99) Total positive results[a] returned								*P. vivax* samples (n=35) 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=99)	Test 1	Test 2	No. positive agreements[c] (max=99)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=40)	Test 1	Test 2	No. positive agreements[c] (max=40)	Test 1	Test 2
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	97.0	95.0 (98)	95.0 (98)	98.0	96.0	96.0	99.0	99.0	1.0	0.0	0.0	1.0	1.0	0.0	34.0	34.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	8.0 (98)	10.0	4.0 (98)	7.0	9.0 (98)	5.0 (98)	77.0	78.0	11.0	14.0	9.0	7.0	6.0 (34)	4.0 (34)	35.0	34.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	96.0	93.0 (98)	92.0 (98)	86.0 (97)	91.0 (98)	82.0 (96)	95.0 (95)	95.0 (98)	30.0 (34)	33.0 (34)	29.0 (33)	24.0 (33)	24.0	19.0 (33)	34.0 (34)	34.0 (34)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	87.0	88.0	82.0	88.0	90.0	84.0	99.0	99.0	4.0	3.0	2.0	1.0	1.0	1.0	34.0	33.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	13.0	14.0	9.0	9.0	12.0	7.0	92.0	91.0	7.0	7.0 (34)	6.0 (34)	4.0	6.0	3.0	35.0	35.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	49.0 (96)	45.0 (95)	39.0 (93)	58.0 (95)	58.0 (97)	48.0 (93)	91.0 (95)	94.0 (98)	32.0 (34)	32.0 (34)	31.0 (34)	31.0 (34)	34.0	31.0 (34)	33.0 (33)	35.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	90.0	92.0	89.0	88.0	91.0	85.0	99.0	99.0	32.0	32.0	30.0	34.0	34.0	33.0	35.0	35.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	68.0	67.0	58.0	61.0	63.0	58.0	96.0	97.0	35.0	35.0	35.0	34.0	35.0	34.0	24.0	31.0 (34)
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	99.0	98.0	98.0	92.0	93.0 (97)	88.0 (97)	99.0	96.0	26.0	27.0	22.0	25.0	27.0	22.0	33.0	32.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	96.0	96.0	95.0	94.0 (98)	95.0 (98)	92.0 (97)	99.0	98.0	35.0	35.0	35.0	34.0	35.0	34.0	35.0	35.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	25.0	27.0	20.0	31.0	30.0	23.0	97.0	94.0	35.0	35.0	35.0	35.0	34.0	34.0	35.0	35.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	87.0	90.0	87.0	89.0	91.0	87.0	99.0	99.0	3.0	2.0	1.0	2.0			35.0	35.0
Pf and Pv																		
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	92.0 (98)	92.0	88.0 (98)	96.0	93.0	92.0	99.0	99.0	2.0	0.0	0.0	2.0	1.0	0.0	5.0	3.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	89.0	86.0	86.0	82.0	81.0	78.0	98.0	99.0	29.0	27.0	25.0	17.0	12.0	11.0	35.0	35.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	95.0	96.0	94.0	95.0	94.0	93.0	99.0	97.0	35.0	35.0	35.0	34.0	35.0	34.0	35.0	35.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	98.0	99.0	98.0	97.0	98.0	97.0	99.0	99.0	32.0	33.0	32.0	27.0	25.0	21.0	35.0	34.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	92.0	92.0	88.0	84.0	82.0	80.0	99.0	99.0	0.0	0.0	0.0	0.0	0.0	0.0	13.0	16.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	91.0	89.0	86.0	92.0	88.0	87.0	99.0	99.0	35.0	35.0	35.0	35.0	34.0	34.0	35.0	35.0
Pf, Pan and Pv																		
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	96.0 (98)	93.0 (97)	92.0 (96)	96.0 (98)	95.0 (98)	93.0 (97)	98.0 (98)	98.0	10.0	8.0	7.0	9.0 (34)	7.0 (33)	6.0 (32)	34.0	34.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	94.0 (96)	96.0 (97)	92.0 (94)	97.0 (98)	94.0 (98)	92.0 (97)	97.0 (97)	98.0	12.0	15.0	9.0	9.0 (34)	8.0	6.0 (34)	34.0 (34)	33.0
Pan only																		
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	90.0	87.0	87.0	89.0 (98)	88.0	82.0 (98)	98.0	98.0 (98)	32.0	30.0 (34)	29.0 (34)	34.0	35.0	34.0	35.0	34.0 (34)
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	34.0	34.0	28.0	25.0 (98)	25.0	18.0 (98)	92.0 (98)	95.0	30.0	27.0 (34)	23.0 (34)	26.0	23.0	22.0	35.0	35.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	34.0 (98)	31.0	23.0 (98)	31.0	34.0	22.0	96.0	90.0 (98)	28.0	26.0	24.0	32.0	28.0	27.0	35.0	35.0

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

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

[b] 8 (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *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.

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=400)					2000[b] parasites/µl Percentage distribution of Pf test band intensity[c] (n=200)					200 parasites/µl Percentage distribution of pan test band intensity[c] (n=400)					2000[b] parasites/µl Percentage distribution of pan test band intensity[c] (n=200)					200 parasites/µl Percentage distribution of Pv test band intensity[c] (n=400)					2000[b] parasites/µl Percentage distribution of Pv test band intensity[c] (n=200)				
			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																																
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	2.8	12.6	53.0	20.2	11.4	0.0	1.0	6.6	14.7	77.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	9.6	14.4	26.3	19.7	30.1	0.5	0.0	2.5	9.1	87.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	9.6	12.1	25.3	13.1	39.9	0.0	1.5	3.5	3.5	91.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	2.3	6.8	15.4	22.2	53.3	0.0	0.0	1.0	3.5	95.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	8.8	13.6	24.2	15.9	37.4	1.0	0.0	2.0	6.1	90.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	13.4	25.8	28.0	22.5	10.4	0.0	2.0	4.6	15.2	78.3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	8.1	14.1	29.8	17.2	30.8	1.0	0.0	3.0	6.1	89.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	17.9	18.2	30.8	13.9	19.2	2.5	1.0	4.6	11.6	80.3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	25.5	21.0	29.3	15.9	8.3	1.5	2.5	11.6	16.2	68.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	6.3	15.9	28.5	34.3	14.9	0.0	0.0	5.1	14.1	80.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	2.5	3.5	14.4	26.3	53.3	0.5	0.0	0.0	4.0	95.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	5.8	12.6	25.3	29.6	26.8	1.0	0.5	1.5	7.6	89.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	9.9	17.9	25.0	23.2	24.0	0.0	1.5	2.5	11.1	84.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	12.6	22.7	29.3	21.2	14.1	0.5	1.0	5.1	16.7	76.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[d]	05FK90	Standard Diagnostics Inc.	5.1 /69.2	8.6 /23.2	15.9 /6.3	23.2 /1.3	47.2 /0.0	0.0 /2.0	0.0 /10.6	3.0 /33.8	3.5 /30.8	93.4 /22.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan																																
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	21.0	20.2	26.5	16.7	15.7	0.5	2.0	5.6	11.1	80.8	98.0	1.5	0.5	0.0	0.0	40.4	26.3	22.7	7.6	3.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	3.5	6.3	15.2	26.5	48.5	0.5	0.0	0.5	4.0	95.0	69.2	25.8	4.0	0.8	0.3	4.0	12.6	31.3	36.4	15.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	8.1	13.1	29.3	22.2	27.3	0.0	0.0	3.5	8.6	87.9	9.6	25.8	35.9	21.5	7.3	0.5	0.0	4.6	26.8	68.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	5.6	10.6	27.3	23.2	33.3	0.0	0.0	1.0	7.1	91.9	8.6	23.5	37.1	22.2	8.6	0.0	0.0	4.0	24.8	71.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
CareStart™ Malaria Screen	GO231	Access Bio, INC.	6.3	9.1	26.0	26.3	32.3	0.0	0.5	4.6	4.6	90.4	9.1	22.7	33.1	23.7	11.4	0.0	0.5	4.6	23.2	71.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	10.6	10.4	29.8	17.2	32.1	0.0	2.0	4.0	6.6	87.4	74.8	12.4	12.1	0.8	0.0	5.1	16.7	38.9	18.2	21.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	17.4	10.4	22.2	18.2	31.8	1.5	2.0	2.0	6.6	87.9	78.3	17.2	3.5	1.0	0.0	9.6	16.2	34.3	27.3	12.6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.8	5.6	21.0	24.8	48.0	0.0	0.0	1.0	4.0	95.0	74.2	18.9	5.1	1.5	0.3	6.1	14.1	37.4	25.3	17.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	7.8	12.4	31.8	13.1	34.9	1.0	0.0	3.5	7.1	88.4	76.8	12.6	10.6	0.0	0.0	3.0	13.6	43.9	20.2	19.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	14.1	12.9	26.0	13.1	33.8	1.0	0.5	3.5	4.0	90.9	71.7	20.2	7.1	0.5	0.5	5.6	14.1	36.4	25.8	18.2	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	19.4	21.5	25.3	20.7	13.1	1.0	2.0	4.0	18.7	74.2	72.2	24.2	2.5	1.0	0.0	5.6	24.2	35.9	24.8	9.6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	24.2	24.8	29.6	13.1	8.3	1.5	1.0	14.1	20.2	63.1	72.2	17.2	10.6	0.0	0.0	25.8	31.3	34.9	7.6	0.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	2.5	9.1	22.7	24.2	41.4	0.0	0.0	2.5	5.1	92.4	99.0	0.3	0.8	0.0	0.0	41.9	30.8	25.3	1.5	0.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Product	Catalogue number	Manufacturer	200 parasites/µl Percentage distribution of Pf test band intensity[c] (n=400)					2000[b] parasites/µl Percentage distribution of Pf test band intensity[c] (n=200)					200 parasites/µl Percentage distribution of pan test band intensity[c] (n=400)					2000[b] parasites/µl Percentage distribution of pan test band intensity[c] (n=200)					200 parasites/µl Percentage distribution of Pv test band intensity[c] (n=400)					2000[b] parasites/µl Percentage distribution of Pv test band intensity[c] (n=200)				
			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
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	91.4	7.6	1.0	0.0	0.0	21.7	28.3	39.4	9.6	1.0	98.7	1.0	0.3	0.0	0.0	54.0	25.8	19.2	1.0	0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	7.1	5.8	22.7	16.2	48.2	2.5	0.0	1.0	2.5	93.9	57.8	21.2	16.4	3.5	1.0	5.1	4.0	32.8	25.3	32.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	10.9	12.6	31.6	14.4	30.6	0.0	0.5	4.0	8.6	86.9	98.7	1.0	0.3	0.0	0.0	57.6	24.2	17.7	0.0	0.5	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	87.9	10.1	1.3	0.8	0.0	7.6	22.2	41.9	17.7	10.6	99.2	0.8	0.0	0.0	0.0	95.5	4.6	0.0	0.0	0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	47.0	22.0	16.2	7.8	7.1	6.6	6.1	11.6	17.7	58.1	70.2	26.5	2.5	0.5	0.3	12.1	19.2	40.4	18.2	10.1	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	8.8	11.9	30.6	31.1	17.7	0.0	0.0	5.1	16.2	78.8	50.5	35.9	12.4	1.3	0.0	2.0	11.6	41.4	34.3	10.6	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	34.6	37.1	26.3	1.3	0.8	2.5	3.5	24.8	25.3	43.9	35.1	38.4	24.5	1.3	0.8	2.0	3.0	27.3	25.8	41.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	3.5	2.3	20.7	15.9	57.6	1.5	0.0	0.0	1.5	97.0	69.4	20.7	8.3	0.8	0.8	7.1	12.6	37.4	23.2	19.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	3.8	8.6	15.9	23.0	48.7	0.5	0.0	0.5	3.0	96.0	56.1	26.5	13.1	3.8	0.5	3.5	3.0	22.2	36.9	34.3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	71.5	20.2	4.0	1.5	2.8	3.5	11.6	30.3	32.3	22.2	76.0	17.9	4.8	1.3	0.0	3.5	13.1	34.9	32.8	15.7	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	9.9	12.4	35.4	22.7	19.7	0.0	0.0	5.6	12.6	81.8	100.0	0.0	0.0	0.0	0.0	82.3	13.6	4.0	0.0	0.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pv																																
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	5.8	19.4	47.0	15.7	12.1	0.0	1.5	8.6	14.7	75.3	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	84.3	12.6	2.5	0.5	0.0	83.8	13.1	3.0	0.0	0.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	14.7	11.6	27.3	19.4	27.0	0.5	1.0	4.6	7.1	86.9	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	99.5	0.5	0.0	0.0	0.0	99.5	0.0	0.5	0.0	0.0
BIONOTE MALARIA P.f.&t P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	4.0	7.1	18.2	26.8	43.9	1.0	0.0	0.5	3.5	95.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	99.8	0.3	0.0	0.0	0.0	97.0	0.5	2.0	0.5	0.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	1.0	5.3	12.6	24.2	56.8	0.0	0.0	0.0	3.0	97.0	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	99.8	0.3	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	11.6	14.4	32.8	16.4	24.8	0.0	1.0	5.1	7.6	86.4	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	9.1	13.4	29.3	29.6	18.7	0.0	0.0	5.1	15.2	79.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	94.7	4.0	1.0	0.3	0.0	78.8	12.6	6.6	2.0	0.0
Pf, Pan and Pv																																
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	4.0	3.5	15.9	22.5	54.0	0.5	0.0	0.0	3.5	96.0	92.7	4.3	1.3	0.3	1.5	24.2	18.7	31.3	21.2	4.6	100.0	0.0	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	3.8	5.8	14.4	22.2	53.8	1.5	0.5	1.0	2.0	95.0	90.9	6.1	0.8	0.5	1.8	19.2	21.7	34.3	16.2	8.6	100.0	0.0	0.0	0.0	0.0	99.0	0.5	0.5	0.0	0.0
Pan only																																
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	10.6	23.2	36.4	21.2	8.6	0.5	0.0	2.0	13.6	83.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	70.2	18.9	9.6	0.5	0.8	5.6	8.1	33.8	24.8	27.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	67.2	18.4	12.4	1.0	1.0	6.1	5.6	37.4	19.2	31.8	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

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

[a] Denotes no visible band

[b] 8 (8%) of the 99 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µl and 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

[c] Calculations include invalid tests

[d] Results for pf-HRP2 line/pf-pLDH line, respectively

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 Percentage distribution of pan or Pv test band intensity[e] (n=140)					2000[b] parasites/µl Percentage distribution of pan or Pv test band intensity[e] (n=70)				
			0[a]	1	2	3	4	0[a]	1	2	3	4
Pf only												
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan												
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	100.0	0.0	0.0	0.0	0.0	27.1	40.0	30.0	2.9	0.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	5.7	32.1	49.3	12.1	0.7	0.0	0.0	0.0	14.3	85.7
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	0.0	9.3	49.3	36.4	5.0	0.0	0.0	0.0	0.0	100.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	1.4	6.4	63.6	23.6	5.0	0.0	0.0	0.0	0.0	100.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	0.7	9.3	60.0	26.4	3.6	0.0	0.0	0.0	2.9	97.1
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	65.0	27.9	7.1	0.0	0.0	0.0	1.4	17.1	28.6	52.9
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	18.7	41.7	33.1	5.8	0.7	1.4	0.0	2.9	10.0	85.7
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	18.6	40.7	39.3	1.4	0.0	2.9	0.0	0.0	14.3	82.9
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	62.9	25.7	10.7	0.7	0.0	0.0	1.4	11.4	35.7	51.4
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	11.4	32.9	43.6	10.7	1.4	0.0	0.0	4.3	5.7	90.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	57.1	36.4	6.4	0.0	0.0	4.3	0.0	31.4	37.1	27.1
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	69.3	19.3	11.4	0.0	0.0	11.4	27.1	51.4	7.1	2.9
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	96.4	3.6	0.0	0.0	0.0	2.9	21.4	61.4	8.6	5.7
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	72.9	25.7	1.4	0.0	0.0	1.4	2.9	55.7	32.9	7.1
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	20.0	27.9	50.0	2.1	0.0	2.9	0.0	5.7	10.0	81.4
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	93.6	6.4	0.0	0.0	0.0	1.4	8.6	58.6	17.1	14.3
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd	82.9	15.0	2.1	0.0	0.0	0.0	4.3	47.1	28.6	20.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	7.9	38.6	44.3	7.9	1.4	2.9	0.0	2.9	8.6	85.7
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	5.7	39.3	48.6	6.4	0.0	0.0	0.0	0.0	27.1	72.9
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.7	1.4	42.1	34.3	21.4	1.4	1.4	0.0	1.4	95.7
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	22.9	28.6	43.6	1.4	3.6	0.0	0.0	4.3	8.6	87.1
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.7	17.1	50.7	27.9	3.6	0.0	0.0	0.0	2.9	97.1
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.7	17.9	51.4	25.0	5.0	0.0	0.0	0.0	1.4	98.6

Product	Catalogue number	Manufacturer	200 parasites/µl Percentage distribution of pan or Pv test band intensity[e] (n=140)					2000[b] parasites/µl Percentage distribution of pan or Pv test band intensity[e] (n=70)				
			0[a]	1	2	3	4	0[a]	1	2	3	4
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	95.0	5.0	0.0	0.0	0.0	0.0	15.7	45.7	32.9	5.7
Pf and Pv												
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	96.4	3.6	0.0	0.0	0.0	88.6	10.0	1.4	0.0	0.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	39.3	27.9	28.6	4.3	0.0	0.0	0.0	1.4	15.7	82.9
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	0.7	10.7	48.6	36.4	3.6	0.0	0.0	0.0	7.1	92.9
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	16.4	19.3	52.9	10.7	0.7	1.4	0.0	0.0	5.7	92.9
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	100.0	0.0	0.0	0.0	0.0	58.6	34.3	7.1	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.7	17.9	56.4	25.0	0.0	0.0	0.0	0.0	2.9	97.1
Pf, Pan and Pv												
Core™ Malaria Pan/Pv/Pf[c]	MAL-190026	Core Diagnostics	95.7	2.1	0.7	0.0	1.4	2.9	20.0	57.1	20.0	0.0
Core™ Malaria Pan/Pv/Pf[d]	MAL-190026	Core Diagnostics	75.7	17.1	6.4	0.7	0.0	2.9	2.9	17.1	40.0	37.1
diagnosticks MALARIA (Pan/Pv/Pf) Cassette[c]	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	90.7	8.6	0.0	0.0	0.7	4.3	18.6	55.7	20.0	1.4
diagnosticks MALARIA (Pan/Pv/Pf) Cassette[d]	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	68.6	20.7	10.0	0.7	0.0	2.9	5.7	17.1	35.7	38.6
Pan only												
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	5.7	32.9	51.4	8.6	1.4	0.0	0.0	5.7	11.4	82.9
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	24.3	36.4	35.7	3.6	0.0	0.0	0.0	0.0	14.3	85.7
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	18.6	25.7	47.9	6.4	1.4	0.0	0.0	2.9	0.0	97.1

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

[a] Denotes no visible band

[b] 2 (6%) of the 35 *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=62)	Asia (n=20)	South America (n=17)	Africa (n=62)	Asia (n=20)	South America (n=17)
Pf only								
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	91.9	100.0	94.1	100.0	100.0	100.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	83.9	90.0	88.2	98.4	100.0	100.0
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	77.4	95.0	94.1	100.0	100.0	100.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	95.2	100.0	100.0	100.0	100.0	100.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	83.9	95.0	88.2	98.4	100.0	94.1
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	79.0	85.0	88.2	100.0	100.0	100.0
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	79.0	100.0	88.2	100.0	100.0	100.0
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	61.3	80.0	76.5	96.8	100.0	94.1
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	61.3	65.0	52.9	98.4	100.0	94.1
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	83.9	85.0	94.1	100.0	100.0	100.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	93.6	100.0	100.0	98.4	100.0	100.0
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	85.5	100.0	94.1	96.8	100.0	100.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	82.3	90.0	88.2	100.0	100.0	100.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	77.4	90.0	82.4	98.4	100.0	100.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[c]	05FK90	Standard Diagnostics Inc.	85.5	90.0	94.1	100.0	100.0	100.0
Pf and Pan								
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	64.5	85.0	70.6	100.0	100.0	94.1
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	91.9	100.0	94.1	98.4	100.0	100.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, INC.	80.7	95.0	82.4	100.0	100.0	100.0
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, INC.	83.9	100.0	94.1	100.0	100.0	100.0
CareStart™ Malaria Screen	G0231	Access Bio, INC.	82.3	100.0	88.2	100.0	100.0	100.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	80.7	95.0	76.5	100.0	100.0	100.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	69.4	70.0	70.6	96.8	100.0	100.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	96.8	100.0	100.0	100.0	100.0	100.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	82.3	90.0	88.2	96.8	100.0	100.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	75.8	85.0	82.4	98.4	100.0	100.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	72.6	90.0	70.6	96.8	100.0	100.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	51.6	65.0	52.9	96.8	100.0	94.1
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	91.9	100.0	100.0	100.0	100.0	100.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	3.2	0.0	0.0	75.8	75.0	47.1
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	83.9	95.0	64.7	96.8	100.0	94.1
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	72.6	85.0	88.2	100.0	100.0	100.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	8.1	5.0	0.0	90.3	95.0	82.4
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	41.9	40.0	17.7	93.6	100.0	94.1
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	79.0	90.0	94.1	100.0	100.0	100.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	50.0	50.0	52.9	96.8	100.0	88.2
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	91.9	95.0	76.5	96.8	100.0	94.1
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	91.9	95.0	94.1	98.4	100.0	100.0

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=62)	Asia (n=20)	South America (n=17)	Africa (n=62)	Asia (n=20)	South America (n=17)
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	24.2	5.0	0.0	95.2	100.0	82.4
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	79.0	95.0	88.2	100.0	100.0	100.0
Pf and Pv								
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	87.1	90.0	82.4	100.0	100.0	100.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	72.6	90.0	82.4	98.4	100.0	100.0
BIONOTE MALARIA P.f.&t P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	90.3	95.0	100.0	98.4	95.0	100.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	96.8	100.0	100.0	100.0	100.0	100.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	74.2	90.0	88.2	100.0	100.0	100.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	82.3	90.0	88.2	100.0	100.0	100.0
Pf, Pan and Pv								
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	90.3	95.0	100.0	98.4	100.0	100.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	93.6	95.0	94.1	98.4	100.0	100.0
Pan only								
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	83.9	85.0	70.6	100.0	100.0	94.1
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	22.6	10.0	0.0	91.9	95.0	94.1
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	24.2	10.0	0.0	95.2	90.0	76.5

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] 8 (8%) of the 99 *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). *P. falciparum* PDS based on individual test lines was : pf-pLDH (25.8, 5, 0% at 200p/µl (Africa/Asia/S.America); 96.8, 95,100% at 2000p/µl (Africa/Asia/S. America) and pf-HRP2 (85.5, 90, 94.1% at 200p/µl (Africa/Asia/S.America); 100, 100, 100% at 2000p/µl (Africa/Asia/S.America))

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=35)					
			200 parasites/µl False positive Pf infection[b] (%)			2000[a] parasites/µl False positive Pf infection[b] (%)		
			Lot 1 (n=70)	Lot 2 (n=70)	Overall (n=140)	Lot 1 (n=35)	Lot 2 (n=35)	Overall (n=70)
Pf only								
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	41.4	38.6	40.0	37.1	34.3	35.7
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	0.0	0.0	0.0	2.9	0.0	1.4
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	1.5 (69)	5.7	3.6 (139)	0.0	2.9	1.4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	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	2.9	2.9	2.9
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	1.4	0.0 (69)	0.7 (139)	0.0	0.0	0.0
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	1.4	0.7	0.0	0.0	0.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	0.0 (68)	0.0	0.0 (138)	0.0 (33)	2.9	1.5 (68)
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	2.9	0.0	1.4
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	2.9	1.4
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[c]	05FK90	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan								
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	0.0	2.9 (69)	1.4 (139)	2.9	0.0	1.4
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	0.0	1.4	0.7	0.0	0.0	0.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	2.9	1.4	2.1	0.0	0.0	0.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	5.7	5.7	5.7	8.6	2.9	5.7
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	0.0 (69)	1.4	0.7 (139)	0.0	2.9	1.4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0 (34)	0.0	0.0 (69)
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	2.9	4.3	3.6	5.7	5.7	5.7
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0	0.0	0.0	2.9	0.0	1.4
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	2.9 (68)	7.1	5.1 (138)	0.0	0.0	0.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	8.6	22.9	15.7	8.6	25.7	17.1
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	14.3	1.4	7.9	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0	0.0 (69)	0.0 (139)	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	0.0 (68)	1.5 (68)	0.7 (136)	0.0 (34)	0.0 (34)	0.0 (68)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	4.3	1.4	2.9	0.0	5.7	2.9
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0 (69)	0.0	0.0 (139)	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0 (68)	0.0 (69)	0.0 (137)	0.0 (33)	0.0	0.0 (68)
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	31.4	8.8 (34)	20.3 (69)
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	2.9	1.4	2.1	5.7	8.6	7.1
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0

Product	Catalogue number	Manufacturer	*P. vivax* samples (n=35)					
			200 parasites/µl False positive Pf infection[b] (%)			2000[a] parasites/µl False positive Pf infection[b] (%)		
			Lot 1 (n=70)	Lot 2 (n=70)	Overall (n=140)	Lot 1 (n=35)	Lot 2 (n=35)	Overall (n=70)
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv								
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	2.9	8.6	5.7	5.7	2.9	4.3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	0.0	1.4	0.7	0.0	0.0	0.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	1.4	1.4	1.4	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pan and Pv								
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.0	0.0 (67)	0.0 (137)	2.9	0.0	1.4
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	0.0	0.0 (69)	0.0 (139)	2.9 (34)	2.9	2.9 (69)
Pan only								
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	N/A	N/A	N/A	N/A	N/A	N/A
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A

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

[a] 2 (6%) of the 35 *P. vivax* dilution sample sets were 200 and 5000 parasites/µl

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

[c] Both pf-HRP2 and pf-pLDH test lines individually returned 0% false positive rates

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=99)					
			200 parasites/µl False positive non-Pf infection (%)			2000[a] parasites/µl False positive non-Pf infection (%)		
			Lot 1 (n=198)	Lot 2 (n=198)	Overall (n=396)	Lot 1 (n=99)	Lot 2 (n=99)	Overall (n=198)
Pf only								
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan								
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	0.0	0.0	0.0	0.0	1.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	0.5	4.0	2.3	0.0	0.0 (98)	0.0 (197)
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	0.0	2.5	1.3	0.0	0.0	6.1
CareStart™ Malaria Screen	GO231	Access Bio, INC.	1.0	2.5	1.8	0.0	0.0	0.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.5
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.0	0.0 (196)	0.0 (394)	0.0	0.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	1.0	0.0 (196)	0.5 (394)	0.0	0.0 (98)	0.0 (197)
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	0.5	3.1 (197)	1.8 (395)	0.0	1.0	0.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	2.0	3.5	2.8	0.0	1.0	0.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	0.0 (197)	0.0	0.0 (395)	0.0	0.0	8.1
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0 (197)	0.0 (197)	0.0 (394)	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	0.5 (197)	1.5 (195)	1.0 (392)	0.0 (95)	0.0 (98)	1.0 (193)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.5	0.5	0.5	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	5.2 (191)	11.5 (192)	8.4 (383)	0.0 (95)	2.0 (98)	0.0 (193)
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	2.5	1.3	0.0	0.0	0.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	2.0	1.0	1.5	1.0	1.0	0.5
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	0.0	2.0 (196)	1.0 (394)	0.0	1.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.0	1.0 (196)	0.5 (394)	0.0	0.0	0.5

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=99)					
			200 parasites/µl False positive non-Pf infection (%)			2000[a] parasites/µl False positive non-Pf infection (%)		
			Lot 1 (n=198)	Lot 2 (n=198)	Overall (n=396)	Lot 1 (n=99)	Lot 2 (n=99)	Overall (n=198)
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	1.0	0.5	0.8	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv								
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	18.3 (197)	13.1	15.7 (395)	16.2	16.2	8.1
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	1.0	0.5	0.0	0.0	0.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	0.0	0.5	0.3	3.0	2.0	1.5
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	0.0	0.5	0.3	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	1.5	9.1	5.3	12.1	30.3	6.1
Pf, Pan and Pv								
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.5 (195)	0.0 (196)	0.3 (391)	0.0 (98)	0.0	0.0 (197)
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	0.0 (193)	0.0 (196)	0.0 (389)	0.0 (97)	0.0	0.0 (196)
Pan only								
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	N/A	N/A	N/A	N/A	N/A	N/A
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	N/A	N/A	N/A	N/A	N/A	N/A
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A

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

[a] 8 (8%) of the 99 *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=100)	Lot 2 (n=100)	Overall (n=200)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	38.0	39.0	38.5	23.8	28.6	26.2	50.0	33.3 (57)	41.7 (115)
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	2.0	2.0	2.0	0.0	0.0	0.0	3.5	3.5	3.5
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	2.0 (99)	0.0 (99)	1.0 (198)	0.0	0.0 (41)	0.0 (83)	0.0	0.0	0.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	3.0 (99)	5.0	4.0 (199)	0.0	0.0	0.0	6.9	6.9	6.9
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	0.0	0.0	0.0	2.4	0.0	1.2	3.5	3.5	3.5
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1.0	1.0	1.0	4.8	4.9 (41)	4.8 (83)	12.1	12.1	12.1
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	5.2	5.2
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	3.0	4.0	3.5	0.0	0.0	0.0	6.9	5.2	6.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	1.0	2.0	1.5	0.0	0.0	0.0	0.0 (57)	0.0	0.0 (115)
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	1.0	0.0	0.5	2.4	2.4	2.4	1.7	0.0	0.9
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	10.3	8.6	9.5
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	2.0	3.0	2.5	2.4	0.0	1.2	8.6	10.3	9.5
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[d]	05FK90	Standard Diagnostics Inc.	2/0	2/0	2/0	0/0	0/0	0/0	0/0	0/0	0/0
Pf and Pan											
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	2.0	4.0 (99)	3.0 (199)	0.0	0.0	0.0	5.2	6.9	6.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.9
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	0.0	6.9	5.2	6.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	5.0	0.0 (99)	2.5 (199)	2.4	0.0	1.2	5.2	8.6	6.9
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	1.0	6.0	3.5	0.0	0.0	0.0	1.7	6.9	4.3
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	0.0	1.0	0.5	7.1	9.8 (41)	8.4 (83)	1.7	1.7	1.7
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	3.0	2.0	2.5	7.1	0.0	3.6	1.7	0.0	0.9
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	2.0	3.0	2.5	0.0	0.0	0.0	3.5	10.3	6.9
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0 (99)	0.0	0.0 (199)	7.1	9.5	8.3	0.0	3.5	1.7
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	1.0	1.0	1.0	0.0	0.0	0.0	3.5	5.2	4.3
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	19.0	30.0	24.5	9.5	4.8	7.1	6.9	29.3	18.1
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	10.0	1.0 (99)	5.5 (199)	0.0 (41)	0.0	0.0 (83)	5.2	3.5	4.3
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0 (99)	0.0 (99)	0.0 (198)	0.0	4.8	2.4	10.3	8.6	9.5
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	1.0 (98)	1.0 (97)	1.0 (195)	0.0	0.0	0.0	1.8 (57)	0.0 (56)	0.9 (113)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	0.0	1.0	0.5	2.4	4.8	3.6	3.5	6.9	5.2
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0 (96)	0.0 (99)	0.0 (195)	0.0	2.4	1.2	7.0 (57)	6.9	7.0 (115)
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	2.0	1.0	0.0	0.0	0.0	3.5	3.5	3.5
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	2.0	2.0 (98)	2.0 (198)	0.0	0.0	0.0	13.8	14.6 (55)	14.2 (113)
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	4.0 (99)	3.0	3.5 (199)	2.4	0.0 (40)	1.2 (82)	0.0	0.0	0.0

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=100)	Lot 2 (n=100)	Overall (n=200)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	3.0	4.0 (99)	3.5 (199)	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	1.0	1.0	1.0	0.0	0.0	0.0	6.9	6.9	6.9
Pf and Pv											
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	18.0	9.0	13.5	7.3 (41)	7.1	7.2 (83)	31.0	19.0	25.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	4.0	4.0	4.0	0.0	0.0	0.0	8.6	6.9	7.8
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	4.0	2.0	3.0	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	0.0	0.0 (99)	0.0 (199)	0.0	0.0	0.0	5.2	3.5	4.3
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	1.0	0.5	0.0	0.0	0.0	3.5	5.2	4.3
Pf, Pan and Pv											
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	3.0	4.1 (98)	3.5 (198)	0.0	0.0	0.0	0.0	1.8 (57)	0.9 (115)
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	3.0	3.0 (99)	3.0 (199)	0.0 (41)	0.0	0.0 (83)	0.0	0.0	0.0
Pan only											
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	4.0	23.0	13.5	0.0 (41)	2.4	1.2 (83)	1.8 (57)	5.2	3.5 (115)
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0

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 for pf-HRP2 line/pf-pLDH line, respectively

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=20)	Lot 2 (n=20)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Pf only										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	0.0	37.5	25.0	15.0	30.0	30.0	50.0	75.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	0.0	0.0	0.0	0.0 (19)	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	0.0	0.0	0.0	0.0	10.0	0.0	0.0	0.0
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	12.5	25.0	5.0	0.0 (19)	0.0	0.0	0.0	0.0
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	0.0	0.0	0.0	5.0	0.0	0.0	25.0	0.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	0.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)a	05FK90	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Screen	G0231	Access Bio, INC.	0.0	0.0	5.0	0.0	0.0	0.0	0.0	0.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	10.0	22.2 (9)	50.0	50.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	20.0	0.0	25.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	20.0	75.0	50.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	0.0	0.0	5.0	10.0	0.0	0.0	0.0	0.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	50.0	50.0	10.0	5.0	10.0	10.0	50.0	50.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	0.0	0.0	0.0 (19)	0.0	0.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	12.5	0.0	0.0	5.0	0.0	10.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	15.0	10.0	20.0	0.0	0.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	37.5	100.0	5.0	70.0	20.0	50.0	0.0	25.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	0.0	0.0 (6)	5.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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=20)	Lot 2 (n=20)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Pf and Pv										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	0.0 (7)	0.0	15.0	0.0	10.0	30.0	0.0	25.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.&t P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	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	MFV-124V	AZOG, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	50.0	50.0	30.0	60.0	20.0	20.0	0.0	0.0
Pf, Pan and Pv										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0 (19)	0.0	0.0	0.0	0.0	0.0
Pan only										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	0.0 (7)	12.5	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	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*

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=18)	Lot 2 (n=18)
Pf only										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	62.5	50.0	57.7	15.4	50.0	66.7	33.3	41.2 (17)
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	25.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pf	MAL-190020	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	0.0	0.0	0.0	0.0	66.7	50.0	0.0	5.6
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	0.0	0.0	0.0	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.	62.5	37.5	0.0	0.0	16.7	33.3	5.6	11.1
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	33.3	33.3	5.6	5.6
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	25.0	12.5	0.0	0.0	33.3	33.3	0.0	0.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	0.0	0.0	0.0 (25)	0.0	0.0	0.0	0.0	0.0
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	12.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	25.0	25.0	0.0	0.0	66.7	50.0	0.0	0.0
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	25.0	25.0	0.0	3.9	50.0	50.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[a]	05FK90	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	25.0	25.0	0.0	0.0	16.7	33.3	0.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	33.3	0.0	0.0
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, INC.	25.0	25.0	0.0	0.0	33.3	16.7	0.0	0.0
CareStart™ Malaria Screen	G0231	Access Bio, INC.	25.0	25.0	0.0	3.9	16.7	33.3	0.0	0.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	25.0	25.0	3.9	7.7	33.3	33.3	5.6	0.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	25.0	25.0	0.0	0.0	16.7	33.3	0.0	0.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	12.5	0.0	3.9	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	25.0	25.0	3.9	19.2	33.3	33.3	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	25.0	37.5	0.0	0.0	0.0	66.7	0.0	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	50.0	50.0	0.0	7.7	66.7	66.7	0.0	0.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	25.0	50.0	11.5	50.0	66.7	83.3	5.6	16.7
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	25.0	25.0	0.0	0.0	50.0	33.3	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	25.0	25.0	0.0	3.9	66.7	33.3	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	25.0	28.6 (7)	0.0 (25)	0.0 (25)	0.0	0.0	5.6	0.0
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	0.0	0.0	0.0	7.7	16.7	16.7	5.6	5.6
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	25.0	50.0	0.0	7.7	50.0	50.0	11.8 (17)	11.1
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	62.5	100.0	19.2	73.1	100.0	100.0	0.0	38.9
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	25.0	25.0	0.0	0.0 (25)	100.0	100.0	0.0	0.0 (16)
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	12.5	0.0	0.0	0.0	16.7	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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=18)	Lot 2 (n=18)
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	25.0	25.0	0.0	0.0	50.0	50.0	0.0	0.0
Pf and Pv										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	50.0	25.0	26.9	15.4	50.0	50.0	50.0	44.4
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	37.5	25.0	0.0	0.0	33.3	33.3	0.0	0.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	0.0	0.0	0.0	0.0 (25)	0.0	0.0	0.0	0.0
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	0.0	0.0	0.0	0.0	50.0	33.3	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	87.5	87.5	53.9	76.9	66.7	66.7	5.6	11.1
Pf, Pan and Pv										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	25.0	12.5	0.0	0.0 (25)	0.0	16.7	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	12.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pan only										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	12.5	0.0	0.0	0.0	0.0 (5)	50.0	0.0	0.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	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] Both pf-HRP2 and pf-pLDH test lines individually returned 0% false positive rates

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=100)	Lot 2 (n=100)	Overall (n=200)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan											
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	2.0	1.0 (99)	1.5 (199)	0.0	0.0	0.0	5.2	6.9	6.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, INC.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.5	1.7
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, INC.	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Screen	G0231	Access Bio, INC.	0.0	0.0 (99)	0.0 (199)	0.0	0.0	0.0	0.0	1.7	0.9
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	8.6	6.9	7.8
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	0.0	1.0	0.5	0.0	0.0 (41)	0.0 (83)	3.5	5.2	4.3
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.0	0.9
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	6.9	8.6	7.8
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	1.0 (99)	0.0	0.5 (199)	0.0	0.0	0.0	3.5	8.6	6.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	1.0	3.0	2.0	2.4	4.8	3.6	13.8	17.2	15.5
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	39.0	47.0	43.0	21.4	19.1	20.2	17.2	43.1	30.2
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	0.0	0.0 (99)	0.0 (199)	0.0 (41)	0.0	0.0 (83)	6.9	6.9	6.9
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	0.0 (99)	0.0 (99)	0.0 (198)	0.0	0.0	0.0	6.9	6.9	6.9
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	0.0 (98)	0.0 (97)	0.0 (195)	0.0	0.0	0.0	3.5 (57)	3.6 (56)	3.5 (113)
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	3.1 (96)	5.1 (99)	4.1 (195)	2.4	11.9	7.1	10.5 (57)	19.0	14.8 (115)
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	13.0	42.0	27.5	14.3	66.7	40.5	27.6	69.0	48.3
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	2.0	2.0 (98)	2.0 (198)	0.0	0.0	0.0	8.6	7.3 (55)	8.0 (113)
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	0.0 (99)	0.0	0.0 (199)	0.0	0.0 (40)	0.0 (82)	3.5	0.0	1.7
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	2.0	2.0 (99)	2.0 (199)	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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=100)	Lot 2 (n=100)	Overall (n=200)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	5.2	5.2
Pf and Pv											
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	13.0	6.0	9.5	7.3 (41)	4.8	6.0 (83)	27.6	22.4	25.0
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f.&t P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	0.0	2.0	1.0	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	0.0	0.0 (99)	0.0 (199)	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	26.0	30.0	28.0	28.6	42.9	35.7	43.1	56.9	50.0
Pf, Pan and Pv											
Core™ Malaria Pan/Pv/Pf[d]	MAL-190026	Core Diagnostics	0.0	0.0 (98)	0.0 (198)	0.0	0.0	0.0	3.5	1.8 (57)	2.6 (115)
Core™ Malaria Pan/Pv/Pf[e]	MAL-190026	Core Diagnostics	0.0	0.0 (98)	0.0 (198)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
diagnosticks MALARIA (Pan/Pv/Pf) Cassette[d]	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	1.0	1.0 (99)	1.0 (199)	0.0 (41)	0.0	0.0 (83)	1.7	0.0	0.9
diagnosticks MALARIA (Pan/Pv/Pf) Cassette[e]	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	0.0	0.0 (99)	0.0 (199)	0.0 (41)	0.0	0.0 (83)	0.0	0.0	0.0
Pan only											
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	4.0	23.0	13.5	0.0 (41)	2.4	1.2 (83)	1.8 (57)	5.2	3.5 (115)
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0

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

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																										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	15.0	0.0	2.0	15.0	0.0	1.9	15.0	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	1.0	15.0	0.0	2.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.2	15.0	0.0	2.0	13.0	2.0	2.0	13.0	0.0	1.9	15.0	0.0	2.7	15.0	0.0	2.2
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	15.0	0.0	2.9	15.0	0.0	2.8	15.0	0.0	2.0	15.0	0.0	2.5	15.0	0.0	1.9	15.0	0.0	2.3	15.0	0.0	2.7	15.0	0.0	2.5
Core™ Malaria Pf	MAL-190020	Core Diagnostics	15.0	0.0	3.2	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	14.0	1.0	4.0	15.0	0.0	4.0	15.0	0.0	3.6
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	15.0	0.0	3.1	15.0	0.0	2.9	15.0	0.0	2.1	15.0	0.0	2.5	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.9	15.0	0.0	2.5
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.0	15.0	0.0	1.3	15.0	0.0	1.9	15.0	0.0	2.0
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	15.0	0.0	2.2	14.0	0.0	2.0	15.0	0.0	2.4	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
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	13.0	0.0	1.0	6.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	5.0	0.0	1.0	1.0	0.0	1.0
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	15.0	0.0	2.0	15.0	0.0	1.7	15.0	0.0	1.4	13.0	0.0	1.2	12.0	0.0	1.6	15.0	0.0	1.5	14.0	0.0	1.4	13.0	0.0	1.5
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	15.0	0.0	2.1	14.0	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	15.0	0.0	2.1
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	15.0	0.0	3.3	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	3.7
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	15.0	0.0	2.3	15.0	0.0	3.0	15.0	0.0	2.7	15.0	0.0	2.8	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	3.0	14.0	0.0	2.5
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	15.0	0.0	2.8	15.0	0.0	2.2	14.0	0.0	2.0	15.0	0.0	2.9	15.0	0.0	2.1	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	2.7
ParaHIT® -f (Dipstick)	55IC101-50	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	1.9	10.0	0.0	1.7	7.0	1.0	1.4	15.0	0.0	1.9	15.0	0.0	1.9
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[b]	05FK90	Standard Diagnostics Inc.	15.0	0.0	2.4/0.0	15.0	0.0	2.0/0.0	15.0	0.0	2.0/0.0	15.0	0.0	2.0/0.0	15.0	0.0	1.9/0.0	15.0	0.0	3.0/0.0	15.0	0.0	2.0/0.0	15.0	0.0	3.0/0.0
Pf and Pan																										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	15.0	0.0	1.7	15.0	0.0	1.0	9.0	0.0	1.0	15.0	0.0	1.0	14.0	0.0	1.1	13.0	0.0	1.1	15.0	0.0	1.0	15.0	0.0	1.5
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	15.0	0.0	2.1	15.0	0.0	3.0	15.0	0.0	3.4	15.0	0.0	2.9	15.0	0.0	2.6	14.0	0.0	2.1	15.0	0.0	3.0	14.0	1.0	3.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.3	15.0	0.0	2.0	15.0	0.0	2.9
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	15.0	0.0	2.9	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	1.8	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.9	15.0	0.0	3.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	1.9	13.0	0.0	2.0	15.0	0.0	2.7	14.0	0.0	2.9	15.0	0.0	2.9
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	15.0	0.0	2.9	15.0	0.0	2.5	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.5	15.0	0.0	2.3
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	15.0	0.0	2.1	15.0	0.0	2.6	15.0	0.0	2.7	15.0	0.0	2.0	14.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.7	15.0	0.0	2.9
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	15.0	0.0	3.0	15.0	0.0	4.0	15.0	0.0	3.9	15.0	0.0	4.0	14.0	1.0	3.9	15.0	0.0	3.3	15.0	0.0	4.0	15.0	0.0	3.3
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	15.0	0.0	2.9	15.0	0.0	2.4	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	14.0	1.0	2.0	15.0	0.0	2.1	15.0	0.0	2.2
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	15.0	0.0	2.2	15.0	0.0	2.8	15.0	0.0	2.9	15.0	0.0	1.9	14.0	0.0	1.9	14.0	0.0	2.0	15.0	0.0	1.8	15.0	0.0	2.8
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.7	15.0	0.0	1.8	15.0	0.0	1.0	15.0	0.0	1.0	14.0	0.0	1.8	15.0	0.0	1.9
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	15.0	0.0	1.0	3.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.2	3.0	0.0	1.3	4.0	0.0	1.3	11.0	0.0	1.3	1.0	0.0	1.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	15.0	0.0	3.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	1.9	15.0	0.0	2.2	15.0	0.0	2.0	15.0	0.0	2.1
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	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
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	15.0	0.0	2.3	14.0	1.0	3.0	15.0	0.0	4.0	15.0	0.0	3.0	14.0	1.0	3.0	15.0	0.0	3.0	15.0	0.0	3.7	15.0	0.0	3.0

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
NanoSign Malaria Pf/Pan Ag	RMAP10	Bioland, Ltd	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	2.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	8.0	0.0	1.0	6.0	0.0	1.8	0.0	0.0	0.0	4.0	0.0	1.0	0.0	0.0	0.0	8.0	0.0	1.0	0.0	0.0	0.0	6.0	0.0	1.3
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	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
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	9.0	0.0	1.0	0.0	0.0	0.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	15.0	0.0	3.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	3.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	15.0	0.0	2.4	15.0	0.0	2.1	14.0	1.0	2.0	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.9	15.0	0.0	2.0	15.0	0.0	3.0
SD BIOLINE Malaria Ag	05FK40	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	15.0	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	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
Pf and Pv																										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	15.0	0.0	2.0	14.0	0.0	1.7	15.0	0.0	1.0	15.0	0.0	1.7	15.0	0.0	1.3	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.8
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	15.0	0.0	2.0	15.0	0.0	3.0	14.0	0.0	2.0	15.0	0.0	2.5	14.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	3.0
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	15.0	0.0	2.1	15.0	0.0	3.0	14.0	1.0	2.9	15.0	0.0	2.8	15.0	0.0	2.5	15.0	0.0	2.0	15.0	0.0	3.0	15.0	0.0	3.0
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	15.0	0.0	3.2	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	14.0	1.0	4.0	15.0	0.0	3.9
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	15.0	0.0	1.6	15.0	0.0	1.6	15.0	0.0	1.9	15.0	0.0	1.5	15.0	0.0	1.7	14.0	0.0	1.3	15.0	0.0	2.0	12.0	0.0	1.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
Pf, Pan and Pv																										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	15.0	0.0	3.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	14.0	1.0	3.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	15.0	0.0	4.0	13.0	2.0	3.9	15.0	0.0	3.8	15.0	0.0	3.8
Pan only																										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	14.0	1.0	1.0	15.0	0.0	1.0	14.0	0.0	1.1	14.0	0.0	1.1	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	2.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech 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	0.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr 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	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] For pan-only tests

[b] Results for pf-HRP2 line/pf-pLDH line, respectively

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																										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pf	MAL-190020	Core Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria Ver. 3	30301025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paracheck® Pf Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	Orchid Biomedical Systems	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® - f (Device)	55IC102-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
ParaHIT® -f (Dipstick)	55IC101-50	Span Diagnostics Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)	05FK90	Standard Diagnostics Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf and Pan																										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	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
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,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	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	15.0	0.0	1.3	15.0	0.0	1.0	15.0	0.0	1.8	15.0	0.0	1.0	15.0	0.0	1.1	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.9
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	15.0	0.0	1.3	15.0	0.0	1.0	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	1.8	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	2.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	15.0	0.0	1.4	15.0	0.0	1.0	15.0	0.0	2.0	15.0	0.0	1.1	13.0	0.0	1.1	15.0	0.0	2.0	14.0	0.0	1.9	15.0	0.0	1.9
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) 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
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) 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
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech 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	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	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	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	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	1.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	0.0	0.0	0.0	4.0	0.0	1.0	9.0	0.0	1.6	7.0	0.0	1.4	7.0	0.0	1.4	5.0	0.0	1.4	6.0	0.0	1.3	2.0	0.0	1.5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	2.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	0.0
NanoSign Malaria Pf/Pan Ag	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
NanoSign Malaria Pf/Pv Ag -	RMAD10	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	1.0	0.0	1.0	0.0	0.0	0.0

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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	10.0	0.0	1.0	10.0	0.0	1.4	12.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	1.0	0.0	1.0	13.0	0.0	1.7	7.0	0.0	1.1	11.0	0.0	1.4	14.0	0.0	1.9	3.0	0.0	1.0	3.0	0.0	1.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	9.0	0.0	1.0	0.0	0.0	0.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr 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	0.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	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	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	05FK40	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (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
Pf and Pv																										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Pf, Pan and Pv																										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	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	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pan only																										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	14.0	1.0	1.0	15.0	0.0	1.0	14.0	0.0	1.1	14.0	0.0	1.1	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.0	15.0	0.0	2.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech 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	0.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr 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	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*

Table A4.12: Heat stability testing results for *P. falciparum* (or pan[a]) test line on a *P. falciparum* samples at high parasite density (2,000 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																										
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	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	4.0	5.0	0.0	4.0	5.0	0.0	4.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	4.0	1.0	4.0	3.0	2.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) 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
Core™ Malaria Pf	MAL-190020	Core Diagnostics	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
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	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
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	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	3.8	5.0	0.0	4.0	5.0	0.0	4.0
NanoSign Malaria Pf Ag	RMAF10	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
One Step Malaria P.F Test (cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	5.0	0.0	3.8	5.0	0.0	2.6	5.0	0.0	2.2	5.0	0.0	2.2	5.0	0.0	1.8	5.0	0.0	1.8	5.0	0.0	3.0	5.0	0.0	2.4
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	2.8	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.4
OnSite Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	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	5.0	0.0	4.0
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria 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 Dipstick- Rapid test for *P. falciparum* Malaria Ver. 3	30302025	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
ParaHIT® - f (Device)	55IC102-50	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	4.0	1.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
ParaHIT® -f (Dipstick)	55IC101-50	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	2.8	5.0	0.0	3.0	5.0	0.0	4.0	5.0	0.0	3.8
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)b	05FK90	Standard Diagnostics Inc.	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.0	5.0	0.0	4.0/1.3	5.0	0.0	4.0/1.4
Pf and Pan																										
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) 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	3.0	5.0	0.0	4.0
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,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/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	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 pLDH 3 Line Test	GO121	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 Screen	GO231	Access Bio, INC.	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	5.0	0.0	4.0	5.0	0.0	4.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) 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
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	5.0	0.0	2.0	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	3.8	5.0	0.0	4.0	5.0	0.0	4.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech 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
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	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	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	5.0	0.0	2.0	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	3.6	5.0	0.0	4.0	5.0	0.0	4.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	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 Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	5.0	0.0	3.8	5.0	0.0	2.6	5.0	0.0	3.0	5.0	0.0	2.0	5.0	0.0	2.6	4.0	0.0	2.0	5.0	0.0	2.4	5.0	0.0	2.8
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, 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 (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	2.0	0.0	1.0	2.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	1.0	0.0	1.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr 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
NanoSign Malaria Pf/Pan Ag	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	4.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
NanoSign Malaria Pf/Pv Ag -	RMAD10	Bioland, Ltd	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	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0

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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	5.0	0.0	3.0	5.0	0.0	3.8	5.0	0.0	3.8	5.0	0.0	3.6	5.0	0.0	3.6	5.0	0.0	3.4	5.0	0.0	3.4	5.0	0.0	3.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, 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
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	4.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	5.0	0.0	2.0	5.0	0.0	2.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr 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
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	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	5.0	0.0	4.0	5.0	0.0	4.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	3.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.2	5.0	0.0	1.8
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) 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	3.8	5.0	0.0	4.0
Pf and Pv																										
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003TC40	InTec Products, Inc.	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.6	5.0	0.0	3.8	5.0	0.0	3.8	5.0	0.0	3.0	5.0	0.0	3.6
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. 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
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,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
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	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 (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, 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	3.8	5.0	0.0	4.0	5.0	0.0	4.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	5.0	0.0	2.0	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
Pf, Pan and Pv																										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	5.0	0.0	4.0	5.0	0.0	4.0	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
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech 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
Pan only																										
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.2	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.2	5.0	0.0	3.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	5.0	0.0	2.0	3.0	0.0	1.3	5.0	0.0	1.8	5.0	0.0	1.8	3.0	0.0	2.0	5.0	0.0	1.6	5.0	0.0	1.6	5.0	0.0	1.6
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	4.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.6	5.0	0.0	1.6	5.0	0.0	1.6	5.0	0.0	1.8	5.0	0.0	1.6

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

[a] For pan-only tests

[b] Results for pf-HRP2 line/pf-pLDH line, respectively

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 Malaria Pan/P.f. Rapid Test Device	IMA-B402	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
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,Inc.	5.0	0.0	1.6	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.3	2.0	0.0	1.0	5.0	0.0	1.0
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	Access Bio, INC.	5.0	0.0	3.6	5.0	0.0	3.0	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.6	5.0	0.0	4.0
CareStart™ Malaria pLDH 3 Line Test	GO121	Access Bio, INC.	5.0	0.0	3.8	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	3.8	5.0	0.0	4.0
CareStart™ Malaria Screen	GO231	Access Bio, INC.	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	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) Ltd	4.0	0.0	1.0	5.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	4.0	0.0	1.0
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) Ltd	5.0	0.0	1.6	0.0	0.0	0.0	5.0	0.0	1.0	4.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	3.0	0.0	1.0
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	5.0	0.0	2.0	5.0	0.0	1.4	4.0	0.0	1.8	5.0	0.0	1.2	4.0	0.0	1.3	5.0	0.0	1.0	5.0	0.0	1.2	3.0	0.0	1.0
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	5.0	0.0	1.0	4.0	0.0	1.0	2.0	0.0	1.0	1.0	0.0	1.0	0.0	1.0	0.0	0.0	0.0	0.0	3.0	0.0	1.0	3.0	0.0	1.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	1.0	3.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0	0.0	1.0	5.0	0.0	1.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	5.0	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	4.0	0.0	1.0	5.0	0.0	1.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	0.0	0.0	0.0	1.0	0.0	1.0	4.0	0.0	1.5	2.0	0.0	2.0	2.0	0.0	2.0	2.0	0.0	1.5	4.0	0.0	1.5	2.0	0.0	1.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-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	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	5.0	0.0	1.4	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.4	5.0	0.0	1.4	5.0	0.0	1.6	5.0	0.0	1.0	5.0	0.0	1.0
NanoSign Malaria Pf/Pan Ag	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
NanoSign Malaria Pf/Pv Ag -	RMAD10	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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	4.0	0.0	1.0	3.0	0.0	1.0	3.0	0.0	1.3	5.0	0.0	1.4	5.0	0.0	2.0	5.0	0.0	2.0	1.0	0.0	1.0	4.0	0.0	1.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	5.0	0.0	1.6	5.0	0.0	1.0	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	2.0	3.0	0.0	1.7	5.0	0.0	1.0	4.0	0.0	1.3
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	4.0	0.0	2.0	0.0	1.0	0.0	0.0	0.0	0.0	5.0	0.0	2.0	5.0	0.0	2.0
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	4.0	0.0	1.0	5.0	0.0	1.0	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	2.0	5.0	0.0	2.0
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	5.0	0.0	2.0	5.0	0.0	1.4	5.0	0.0	1.0	2.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.2	5.0	0.0	1.0
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	5.0	0.0	1.0	3.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.2	5.0	0.0	1.4
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (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
Pf, Pan and Pv																										
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	3.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	0.0	1.0	0.0	3.0	0.0	1.0	4.0	0.0	1.3	4.0	0.0	1.0	3.0	0.0	1.0
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	5.0	0.0	1.0	2.0	0.0	1.5	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	1.0	4.0	0.0	1.0	3.0	0.0	1.3	3.0	0.0	1.0

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

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

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																		
Advanced Quality™ One Step Malaria P.f Test	ITP11002TC40	InTec Products, Inc.	1.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	4.0	0.0	0.0	0.0	1.0	0.0
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,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
Clearview® Malaria P.f.	VB01	Vision Biotech (Pty) 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
Core™ Malaria Pf	MAL-190020	Core Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria P.f.	ML01	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	0.0	0.0	0.0	0.0	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 Ag	RMAF10	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
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
One Step Malaria P.f Test	W37-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	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
OnSite Pf Ag Rapid Test	R0114C	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
Paracheck® Pf Device- Rapid test for *P. falciparum* Malaria 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 Dipstick- Rapid test for *P. falciparum* Malaria 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
ParaHIT® - f (Device)	55IC102-50	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
ParaHIT® -f (Dipstick)	55IC101-50	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	1.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[a]	05FK90	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 Pan																		
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	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
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit	RG19-08	Bionote,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/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	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 pLDH 3 Line Test	GO121	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 Screen	GO231	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
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) 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
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) 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
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech 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
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	0.0	0.0	1.0	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
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	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	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-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	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	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
NanoSign Malaria Pf/Pan Ag	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
NanoSign Malaria Pf/Pv Ag -	RMAD10	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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	1.0	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
OnSite Pf/Pan Malaria 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
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	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
Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr Biomedical Systems	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
SD BIOLINE Malaria Ag P.f/Pan	05FK60	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	05FK40	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
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (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
Pf and Pv																		
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, 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
Advantage Malaria Card	IR211025	J. Mitra & Co. 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
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,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 Pv/Pf	MAL-190022	Core Diagnostics	0.0	0.0	0.0	0.0	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	MFV-124V	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
OnSite Malaria 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	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pan and Pv																		
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	1.0	0.0	0.0	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
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech 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
Pan only																		
Clearview® Malaria pLDH	70884025	Orgenics Ltd. (Inverness Medical Innovations)	1.0	0.0	2.0	0.0	0.0	0.0	2.0	0.0	4.0	0.0	4.0	0.0	0.0	0.0	4.0	0.0
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech 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
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr 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

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

[a] Both pf-HRP2 and pf-pLDH test lines individually returned 0% positivity rates

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 Malaria Pan/P.f. Rapid Test Device	IMA-B402	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
BIONOTE MALARIA P.f.&t Pan Ag Rapid Test Kit	RG19-08	Bionote,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/Pregnancy Combo (pLDH/HRP2/HCG)	GO221	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 pLDH 3 Line Test	GO121	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 Screen	GO231	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
Clearview® Malaria Combo	VB11	Vision Biotech (Pty) 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
Clearview® Malaria Dual Test Device	VB20	Vision Biotech (Pty) 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
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech 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
ICT Diagnostics Malaria Combo	ML02	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Diagnostics Malaria Dual	ML03	ICT Diagnostics	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.0
Malaria Pan Test	MAL-W23N-001	Dima • Gesellschaft für Diagnostika mbH	0.0	0.0	2.0	0.0	1.0	0.0	2.0	0.0	2.0	0.0	4.0	0.0	2.0	0.0	2.0	0.0
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	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	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-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	0.0	0.0	0.0	0.0
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	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
NanoSign Malaria Pf/Pan Ag	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
NanoSign Malaria Pf/Pv Ag -	RMAD10	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
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	1.0	1.0	0.0	0.0	1.0	0.0	1.0	4.0	0.0	4.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Malaria Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	3.0	0.0	3.0	0.0	3.0	0.0	3.0	0.0	1.0	0.0	0.0	0.0
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	0.0	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™ Device - Rapid test for Malaria Pan/Pf	50310025	Zephyr 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
SD BIOLINE Malaria Ag P.f/Pan	05FK60	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	05FK40	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
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (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
Pf, Pan and Pv																		
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	0.0	0.0	0.0	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
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech 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

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

Annex 5a: Selection of an appropriate RDT

Step 1.1
Define setting of use

What ? target parasite species and antigen[a]

Pf or mixed Pf/non-Pf infections:	Pf or non-Pf infections[b]:	*P.vivax*, only:
- HRP2 - pLDH-Pf	- HRP2, aldolase ; HRP2, pLDH-pan - HRP2, pLDH-Pv; HRP2, pLDH-Pvom - HRP2, pLDH-pan; pLDH-Pv - pLDH-Pf, pLDH-pan; pLDH-Pf, pLDH-Pv - pLDH-Pf, pLDH-P vom	- aldolase - pLDH-pan - pLDH-Pv

****Pf with absent HRP2 – DO NOT USE HRP2 based RDTs[c]**

Where ?	Exposure high temperature eg. tropical environment OR Temperature controlled environment, including during transport and storage
Who?	Laboratory personnel OR Health workers outside of laboratories

↓

Step 1.2
Review RDT performance

WHO RDT Product Testing results[d] and apply WHO recommended RDT selection criteria[e]

- Panel Detection Score (PDS)
- False Positivity Rate (FPR)
- Invalid Rate (IR)
- Ease of use
- Thermal stability
- Ease of use

↓ ← Sensitivity and specificity based on quality field studies in relevant populations

Generate RDT short list

Step 1.3
Apply national guidelines and experience in use of RDTs

National malaria treatment guidelines

↓

In-country experience: ease of use assessments (Annex 5b); availability of training materials

Step 1.4
Other considerations

- Price
- Supplier's: production capacity, lead times, heat stability data
- Delivery schedules (eg. staggered deliveries), box size, shelf life
- Registration requirements of a national regulatory authorities
- Product lot testing results
- Overall budget requirements (Annex 6)

[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 (2010); FIND Malaria RDT Product Testing: Interactive Guide - *http://www.finddiagnostics.org/programs/malaria/find_activities/product_testing/malaria-rdt-product-testing/*

[e] WHO RDT procurement criteria : *http://www.who.int/malaria/diagnosis_treatment/diagnosis/RDT_selection_criteria.pdf* (accessed 6 September, 2011)

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: RDT format review and ease of use assessment

Obtain samples of each malaria RDT under consideration (at least 1 box packaged as intended for final delivery)

Obtain negative blood samples, and where readily accessible, parasite positive blood samples for testing against RDTs. The purpose of an evaluation on a limited number of tests is to assess aspects of ease-of-use and to screen for major test anomalies, as described in the table below, **and not to assess diagnostic accuracy**.

Device and components of kit	Features to look for in product review and ease-of-use assessment
Test strip	• Good clearance of blood by time of reading • Even flow of blood up strip
Test lines	• 'ghost line' – sometimes a faint line can be seen before the test is used • False-positives: blood products stick to line, giving an impression of a positive result • Very thin or incomplete lines in positive cases, or spreading of line colour along strip ('leaching')
Control lines	• As with test lines
RDT buffer	• Variable drop size • Leakage from bottles • Overflow of buffer from well on cassette when correct number of drops are applied.
Structural issues	Shifting of strips inside cassette
Blood transfer device	• Blood safety features • Ease-of-use
Other QC issues	a) Not enough buffer provided b) No test tubes provided c) Cassette is damaged/Missing parts d) Cassette has no identifiers e) Box is missing instructions/Instructions aren't clear f) Condition of boxes – those without natural disaster excuses g) Tests aren't always "easy open"

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 systematic approach to planning, implementation, monitoring and evaluation of the diagnostic programme; a process that must commence well before RDTs are procured. Examples of widescale successful introduction of malaria RDTs are now in existence in various national programmes *(26)*. The following information is derived from existing WHO documents addressing this area.[27] A malaria RDT Implementation manual to guide national programmes in this area is nearing completion and will be accessible at *www.wpro.who.int/sites/rdt* and *www.finddiagnostics.org/resource-centre/reports_brochures/*.

Many health workers and communities will have been taught 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 (detailed elsewhere on this website). 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.

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. If changing from a different product or mode of diagnosis, an adequate phase-out plan for this must also be developed.

This requires a clear strategic plan to be developed well in advance of RDT introduction, with a clear timeline to ensure that the various components of the RDT programme are in place at the right time. A focal person, or persons, will be needed to coordinate the overall implementation plan and ensure that the various agencies that may be involved understand the process and their particular roles. To achieve this, funding for the programme must include a significant component for planning and coordination, sensitization/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.

An example of a national implementation plan is shown on the following pages. This will need to be modified considerably for each programme, preferably through a collaborative process involving all the major agencies concerned in its implementation. Budgeting for all the components of the programme at the outset is vital. An example of components to be considered in an overall budget is shown in Figure A6.1.

[27] Developed by WHO Regional Office for the Western Pacific and the WHO Global Malaria Programme, with support from the Uganda Ministry of Health (National Malaria Control Programme), Management Sciences for Health (MSH), and other partners.

Summary of introduction plan (see following page)

Program planning and management

- Identify key stakeholders, and secure commitment for introduction of RDTs
- Establish working group and develop terms of reference
- Identify specific focal person(s) responsible for day to day oversight of the implementation plan
- Develop a timeline, scope, and budget for implementation
- Identify human and other resource needs, and a strategy for accessing them
- Review and update, if needed, case-management algorithms for malaria and other causes of febrile illness

Policy and regulatory issues

- Develop appropriate regulatory documents if required
- Register RDT products

Procurement of RDTs

- Develop product specifications and packaging requirements
- Develop product short-list
- Conduct quantification (estimation of needs)
- Procure RDTs
- Procure sharps boxes, gloves etc.

Logistics

- Develop distribution plan
- Train logistics and storage personnel in handling and distribution of RDTs
- Implement a system for data collection and information flows
- Arrange for appropriate transport and storage
- Review and strengthen inventory management, as needed
- Develop a plan for discontinuation and disposal of other diagnostic supplies, if appropriate

Quality Assurance

- Develop mechanisms for assessing samples at a national level (lot-testing), and regular (and random) testing at the level of use (e.g. microscopy-sentinel sites)
- Implement post-marketing surveillance

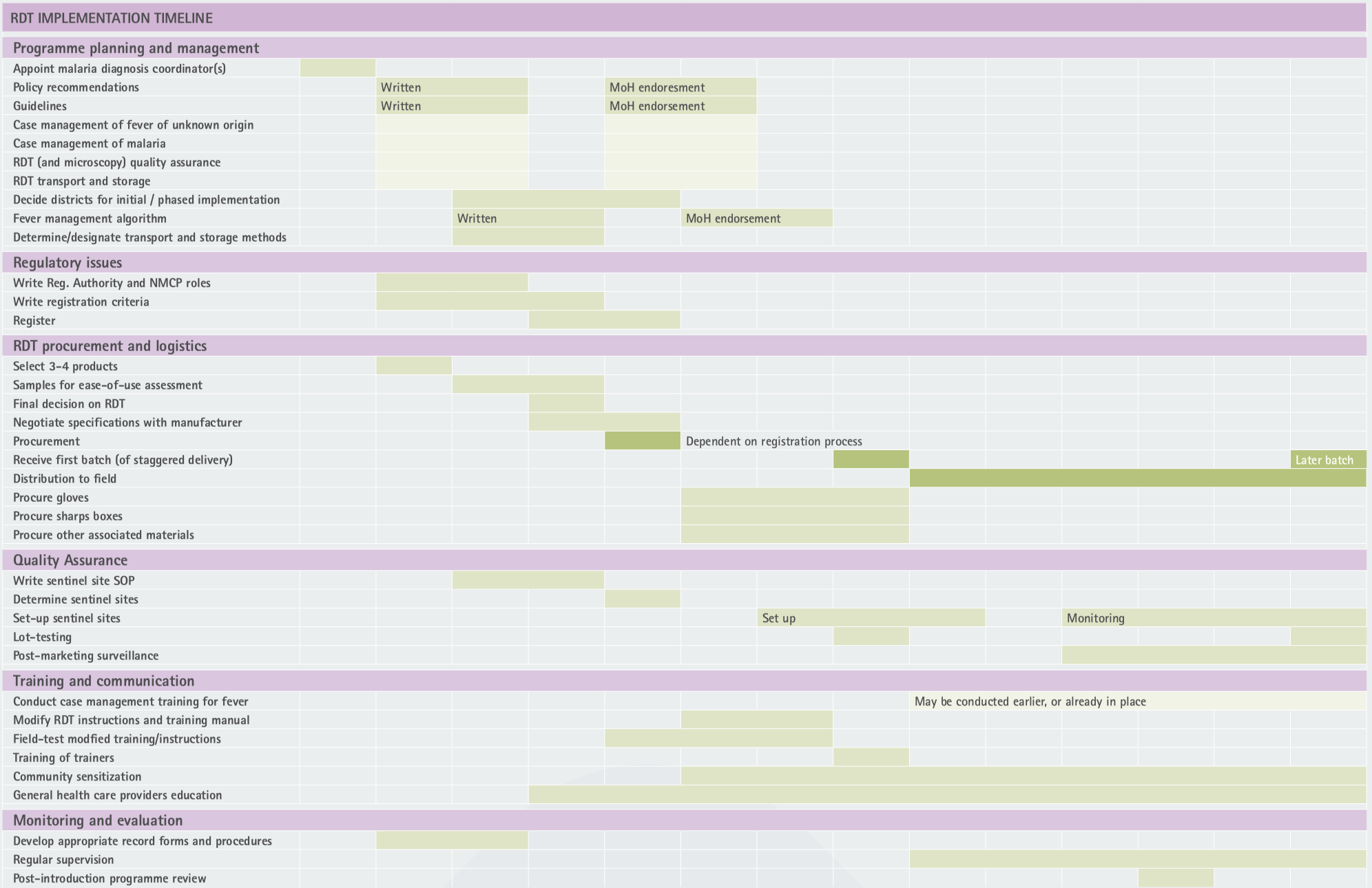
Training and communication

- Develop appropriate training and supervision materials
- Train health workers in case management and managing commodities
- Train in RDT use
- Develop and implement a program for community education/ sensitization

Monitoring and Evaluation

- Implement effective supervision and monitoring
- Strengthen recording and reporting procedures

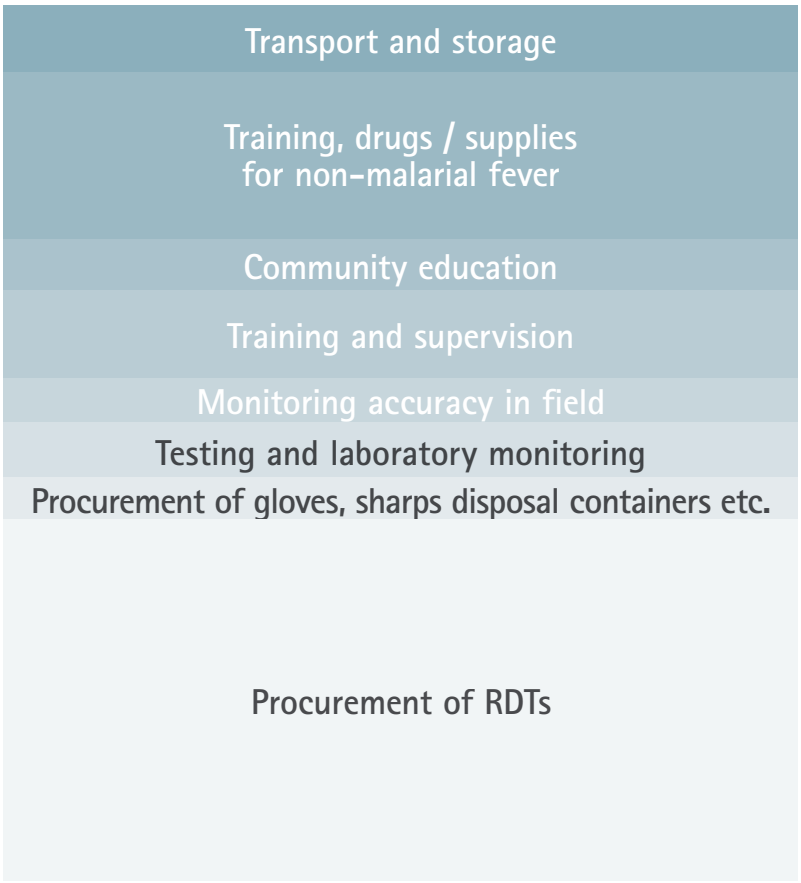
Recommended sequence of activities for implementation of RDT-based diagnosis in a national malaria programme and the relative time allotment.[a]



[a] time requ irements will vary between programmes

Figure A6.1 Example malaria RDT implementation budget

Below is an example of major components of a programme budget to be considered when introducing RDTs into a malaria programme. Without adequate provision for each of these factors, it is likely that an RDT-based diagnostics programme will fail to achieve its goals. These components should therefore be addressed in proposals for programme funding, or provisions should be made for them in collaborating programmes.



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