Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: Round 5 (2013)

World Health Organization

FIND
foundation for innovative new diagnostics

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The WHO Programme of Prequalification of Diagnostics and Medical Devices uses the results of the WHO Malaria RDT Product Testing Programme as the laboratory evaluation component of the prequalification process for malaria RDTs. Although not currently a requirement for WHO procurement, manufacturers are encouraged to apply for WHO prequalification. A regularly updated list of WHO-prequalified diagnostics, including malaria RDTs, is available at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/*.

WHO recommendations for procurement of malaria RDTs are currently based on the attainment of a set of minimum performance criteria in the WHO Malaria RDT Product Testing Programme. These recommendations were established by the WHO Malaria Policy Advisory Committee in 2012 , are outlined in this report and presented in full in a WHO information note (available at *http://www.who.int/malaria/publications/atoz/rdt_selection_criteria_en.pdf?ua=1*).Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO.

The lists of RDTs included in this report are not exhaustive lists of malaria RDTs. These lists reflect those products which have been submitted for evaluation in Rounds 2-5 of the WHO Malaria RDT Product Testing Programme, and indicate to what extent these products, as manufactured by the listed companies, were -at the time of their evaluation- found to meet the above mentioned set of minimum performance criteria. The evaluation results indicated in the figures and tables apply only to the specific product as listed with its unique product code / catalogue number and as manufactured by the listed company.

The improper storage, transport and handling of malaria RDTs may affect their level of performance.

The fact that certain products are not included in the lists and figures in this report indicates that they have not or not yet been submitted for evaluation in the WHO Malaria RDT Product Testing Programme, or that their evaluation has not yet been completed and published in [a new edition of this report]. It does not however indicate anything in respect of such products' performance. The lists and figures are updated regularly, and malaria RDTs are added to the lists and figures as and when (following the voluntary participation in the WHO Malaria RDT Product Testing Programme) their evaluation against the above mentioned set of minimum performance criteria has been completed.

Although the malaria RDTs listed in the tables and figures are regularly re-evaluated, and updated evaluation results are published by WHO, WHO cannot represent that products included in the lists and figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that before procurement of a malaria RDT, each lot of that product undergoes lot testing at one of the two following lot-testing laboratories: Institut Pasteur du Cambodge (IPC), Cambodia or Research Institute for Tropical Medicine (RITM), The Philippines.

WHO disclaims any and all liability and responsibility whatsoever for any injury, death, loss, damage, or other prejudice of any kind that may arise as a result of or in connection with the procurement, distribution and use of any product included in this report and the figures and tables listed on pages V-VII.

This report may not be used by manufacturers and suppliers for commercial or promotional purposes.

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ACKNOWLEDGEMENTS

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ABBREVIATIONS

CDC	United States Centers for Disease Control and Prevention
ELISA	enzyme-linked immunosorbent assay
FIND	Foundation for Innovative New Diagnostics
HRP2	histidine-rich protein 2
ISO	International Organization for Standardization
PCR	polymerase chain reaction
PDS	panel detection score
pLDH	*Plasmodium* lactate dehydrogenase
Pf	*Plasmodium falciparum*
Pv	*Plasmodium vivax*
Pvom	*Plasmodium vivax, ovale, malariae*
RDT	rapid diagnostic test (for the purposes of this report, immunochromatographic lateral flow devices for the detection of malaria parasite antigens)
TDR	Special Programme for Research and Training in Tropical Diseases sponsored by UNICEF, UNDP, the World Bank and WHO

1. SUMMARY OF PERFORMANCE OF RAPID DIAGNOSTIC TESTS FOR MALARIA: WHO PRODUCT TESTING ROUNDS 1–5

1.1. Introduction

WHO estimates that half the world's population is at risk of malaria. In 2012, there were an estimated 207 million cases (with an uncertainty range of 135 million to 287 million) and an estimated 627 000 deaths (with an uncertainty range of 473 000 to 789 000). Approximately 90% of all malaria deaths occur in sub-Saharan Africa, and 77% occur in children under 5 years. Malaria remains endemic in 104 countries, and, while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly confirmed, resulting in over-use of antimalarial drugs and poor disease monitoring (*1*).

WHO recommends that malaria case management be based on parasite diagnosis in all cases (*2*). The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained. The number of RDTs available and the scale of their use have increased rapidly over the past few years; however, limitations of field trials and the heterogeneous nature of malaria transmission have limited the availability of the good-quality data on performance that national malaria programmes require to make informed decisions on procurement and implementation, and it is difficult to extrapolate the results of field trials to different populations and times. Therefore, in 2006, the WHO Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched a programme to systematically evaluate and compare the performance of commercially available malaria RDTs. The results of WHO's malaria RDT product testing have been published annually since 2009 and form the basis of the procurement criteria of WHO, other United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria, national governments and nongovernmental organizations. The data have guided procurement decisions, which, in turn, have shifted markets towards better-performing tests[1] and are driving overall improvements in the quality of manufacturing.

This summary presents an overview of the results of rounds 1–5 of malaria RDT product testing and key concepts for understanding and using the results. It is published in conjunction with the release of the full report on round 5. The results of all rounds of testing should be considered as a single data set. The separate, full reports of each round (*3*–*6*) should be consulted for further details of methods, product performance and interpretation of the results.

1.2. The WHO product testing programme

The RDT evaluations summarized here were performed in collaboration by WHO, TDR, FIND, the United States Centers for Disease Control and Prevention (CDC) and other partners.[1] All companies that manufacture according to the ISO 13485:2003 quality system standard were invited to submit one to three products for evaluation in the programme. In each round of testing, products are evaluated against geographically diverse, cryopreserved *Plasmodium falciparum* and *P. vivax* clinical samples diluted to 200 and 2000 parasites/μL and with consistently comparable concentration ranges of histidine-rich protein II (HRP2), *Plasmodium* lactate dehydrogenase (pLDH) and aldolase determined by quantitative enzyme-linked immunosorbent assay (ELISA) (Annex S1). In the first round of testing, 41 products from 21 manufacturers were evaluated against prepared blood panels of cultured *P. falciparum* parasites, while 29, 50, 48 and 42 products from 13, 23, 27 and 34 manufacturers were evaluated in rounds 2, 3, 4 and 5, respectively. Of these 210 products, 206 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites and a parasite-negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive assessment of ease of use was made. Many manufacturers have decided voluntarily to submit products to one or more rounds of testing, and, in round 5, a requirement was instituted to resubmit products for re-evaluation within 5 years of original testing (Table S1). Of the 206 fully evaluated products, 32 have been evaluated twice, 11 have been evaluated three times and two evaluated four times in rounds 1–5. Of the 147 unique products tested in the programme, 36 detect *P. falciparum* alone, 101 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific for *P. vivax* or *P. vivax*, *ovale* and *malariae*), 9 detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them, and one product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation. When the same products (*7*) were resubmitted in subsequent rounds of testing, the second set of results replaced those from the earlier round. Thus, the performance of some tests in the results below differs from that reported in rounds 1–4.

Of the 22 products due for compulsory retesting in round 5, 10 were submitted (Table S1). Round 1 products that were not

[1] See full reports of rounds 1–5 (3–6) for lists of collaborating partners.

resubmitted have been removed from the figures and tables in this summary performance document.

The aim of the evaluation is to provide comparative data on the performance of the submitted production lots of each product. These data will be used to guide procurement decisions by WHO, other United Nations agencies and national governments and constitute the laboratory evaluation component of the WHO prequalification process for malaria RDTs (*8*). Product testing is part of a continuing programme of work to improve the quality of RDTs in use and to ensure reliable malaria diagnosis in areas where malaria is prevalent. A sixth round of product testing will begin in June 2014.

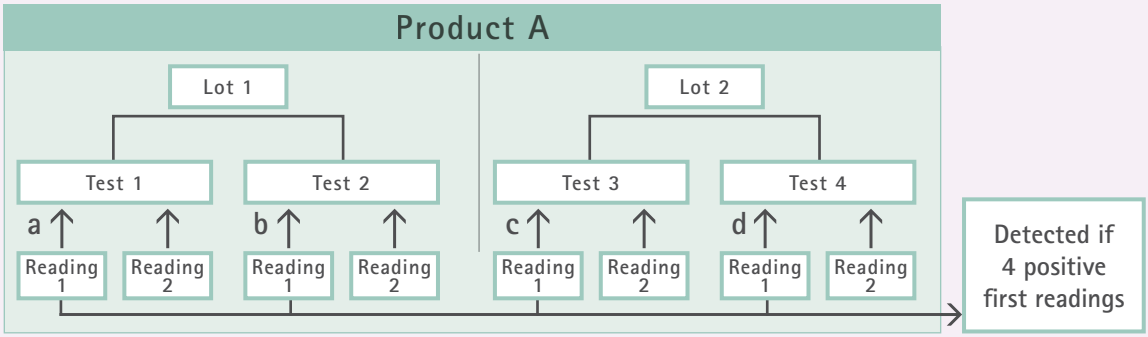
1.3. Panel detection score and other results of the evaluation

The results (summarized in Figs S1–S3 and Tables S2 and S3) 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 is considered close to the threshold that must be detected in order reliably to identify clinical malaria in many settings (*9*). For the purposes of this report, the main measure of performance is the panel detection score (PDS);[1] for each RDT evaluated, the PDS is measured separately at the

[1] Termed "detection rate" in the full report of round 1, published in 2009.

Box 1: Example calculation of panel detection score and positivity rate 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 30 min later[a]. A sample is considered detected only if all first test readings, from both lots, are positive, i.e. readings a, b, c and d must be positive.



[a] second reading results are for internal use only

P. falciparum sample	a	b	c	d	
1	+	–	+	+	Sample NOT detected
2	+	–	–	+	Sample NOT detected
3	+	+	+	+	Sample detected

In this example, only one of three samples was positive all four times it was tested; the PDS is therefore 1/3 = 33%.

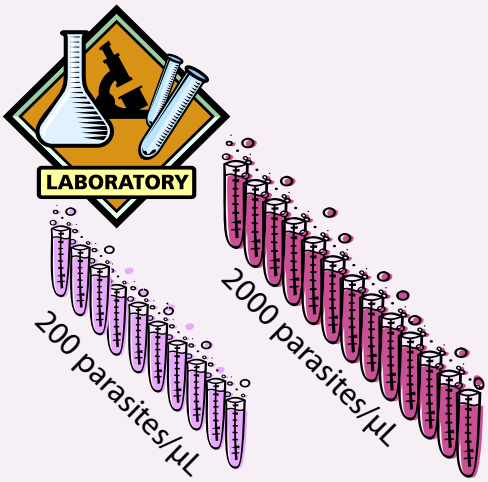
The positivity rate is calculated as the percentage of all tests of a particular product that returned a positive test result at the manufacturers' recommended minimum reading time when tested against a *P. falciparum* or *P. vivax* sample.

In the above example, the positivity rate is: 9/12 = 75%.

The positivity rate is always greater than the PDS, except when the PDS and the positivity rate are both 100%.

Box 2: Performance measures in WHO product testing and in field settings: PDS versus clinical sensitivity

WHO Malaria RDT Product Testing
Primary performance measure: PDS indicates which products are likely to be more sensitive in the field, particularly in populations with low-density infections.



Reference panels: two fixed parasite densities allows discrimination in RDT performance.

Malaria endemic setting
Performance measure: sensitivity is the proportion of the population studied who have malaria for whom the test is positive.

- high, moderate, low transmission
- immune, non-immune
- vulnerable groups

Patients have varying parasite density. Most RDTs for *P. falciparum* and *P. vivax* perform well for a parasite density > 2000 parasites/µL, but clinically significant densities < 200 parasites/µL may be missed. The "overall" test performance will nevertheless be classified as very good in a field evaluation.

lower and the higher parasite density. The summary figures also show the false-positive rates against blood samples containing no malaria parasites or known markers of other diseases and the rate of invalid results.

The PDS is the percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or by a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density, it must show a positive result in four tests (two RDTs per lot for two lots); at the higher parasite density, it must show a positive result in two tests (one RDT per lot for two lots). Thus, the PDS is a combined measure of positivity rate, incorporating inter-test and inter-lot consistency. As all tests performed on each sample must show a positive result for the sample to be considered positive, the PDS for a given RDT will usually be lower than a simple positivity rate per panel, measured by comparing the number of positive tests among all tests performed per panel. The PDS is also different from clinical sensitivity: the ability of the test to detect malaria infection in a given population of infected patients. Boxes 1 and 2 illustrate how the PDS is calculated and how it differs from a simple positivity rate for all samples tested and from clinical sensitivity in a population.

The PDS for a given RDT is different from the clinical sensitivity of that RDT (also called the true positive rate), which is a measure of the proportion of people known to have the disease who test positive for it. The sensitivity of malaria RDTs is highly dependent on local conditions, including the parasite density in the population; it therefore varies among populations with different levels of transmission, as their level of immunity affects the parasite density at which they exhibit symptoms that warrant a diagnostic test. Where transmission rates are low, the parasite densities in people with symptoms of malaria are likely to be low, and tests will be less sensitive. Test performance at 200 parasites/µL is therefore particularly important. The results in this report show the comparative performance of RDTs and indicate which products are likely to be more sensitive in the field, particularly in populations with low-density infections.

In general, as countries reduce the prevalence of malaria and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the high PDS at 2000 parasites/µL indicates, the sensitivity of many of these products is similar in populations with higher parasite densities and therefore it is not possible to discriminate RDTs with superior performance.

An important caveat to estimating field sensitivity from the PDS provided in this report is that the panels used include only 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 that infect people in some areas of South America and India do not express HRP2 (*10*, *11*). In areas where HRP2-deleted parasites exist, tests for HRP2 will have greatly reduced sensitivity or be incapable of detecting *P. falciparum*. In such populations, only tests for pLDH or aldolase in *P. falciparum* parasites will be effective for diagnosing falciparum malaria.

Heat stability (summarized in Table S3) is vital to maintaining the sensitivity of tests in the field. As a result, for procurement, careful consideration must be given to ensure that the products to be used in areas with high temperatures of transport and storage have demonstrated stability in the product testing programme. Requirements vary among countries; for example, if tests are to be deployed in areas where temperatures rarely rise above 30 °C, less emphasis is needed on stability at high temperatures than on other aspects of quality.

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

Detailed results can be found in the report of each evaluation (*3*–*6*) and at http://www.who.int/malaria/publications/diagnostic_testing/en/.

1.4. Summary of outcomes

This laboratory-based evaluation provides a comparative, standardized measure of RDT performance for distinguishing between well and poorly performing tests to serve as a basis for procurement decisions by malaria control programmes and to guide United Nations procurement policy.

In round 5, the proportion of tests that achieved a PDS ≥ 75% at 200 parasites/µL is comparable to those in rounds 3 and 4 for *P. falciparum* (78.6%); that for *P. vivax*, 42.4%, is similar to that in round 4.

Several RDTs in the five rounds of testing consistently detected malaria at a low parasite density (200 parasites/µL), had low false-positive rates, are stable at tropical temperatures, are relatively easy to use and can detect *P. falciparum* or *P. vivax* infections or both.

Although the performance of the products varied widely at low parasite density (200 parasites/µL), all products had a high rate of detection of *P. falciparum* at 2000 or 5000 parasites/µL, as did the majority of products for *P. vivax* at 2000 parasites/µL.

P. falciparum tests that target the HRP2 antigen had the highest detection rates, and two previously evaluated tests that target pan-pLDH for detection of *Plasmodium spp.* infection also achieved a good PDS. In round 5, the two poorest performing tests for detection of *P. falciparum* were based on *P. falciparum*-specific pLDH detection. Thus, the choice of well-performing pLDH-based *P. falciparum* tests remains limited, as it does for pan-only-specific tests.

Test performance sometimes varied between lots and widely between similar products, confirming the advisability of testing lots after purchase and before use in the field. Furthermore, anomalies that interfered with test interpretation were regularly recorded during round 5 (Annex S2). All products had issues with red background and with incomplete clearing, and cases of samples failing to flow or migrate on the RDT were reported for 62% of products.

Ninety-eight percent of the RDTs evaluated in round 5 were in cassette format.

With regard to products retested under the compulsory resubmission requirement, one showed improved (4.8%) detection of *P. falciparum* and one improved (4.3%) detection of *P. vivax*, while six and two had diminished performance (> 5% decrease) for detection of *P. falciparum* (mean, 13.9%; median, 8.4%) and *P. vivax* (mean, 8.5%), respectively. All products except one had the same or lower false-positive rates (mean improvement, 3.7%).

1.5. How can product testing results inform RDT procurement and use?

Accurate diagnosis is vital to good malaria case management, whether based on microscopy or RDTs. The results of this report should be used to identify a short list of RDTs for procurement for use in settings where good microscopy is not available or appropriate. Box 3 lists WHO's minimum criteria for RDT selection, and Annex S3 provides a step-by-step approach to selecting an RDT, taking into consideration local malaria transmission and illness where the tests will be used (e.g. *Plasmodium* species, target antigen, parasite densities, climate) and other important considerations, including ease of use in the field (Annex S2), training or retraining requirements and lot testing.[1]

The tabular results in TableS2 are colour-coded to reflect achievement of WHO performance requirements for RDT procurement, and a web-based tool that allows filtering of product testing results by various parameters to assist in selecting products with the performance characteristics most suitable for a country's health programme is available and maintained by FIND (*12*). Comprehensive guidance on several aspects of procurement can be found in *Good practices for selecting and procuring rapid diagnostic tests for malaria* and guidance on implementation in *Universal access to malaria diagnosis* (*13*, *14*).

1.6. Product testing and WHO programme for prequalification of diagnostics and medical devices

The WHO prequalification of diagnostics and medical devices programme uses the results of product testing as the laboratory evaluation component of the prequalification process for malaria RDTs. These data are used to set priorities for dossier review and inspection. Although prequalification is not currently a requirement for WHO procurement, manufacturers are encouraged to apply for it. A list of prequalified diagnostics, including malaria RDTs, is available at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/*.

[1] The WHO-FIND malaria RDT evaluation programme provides lot-testing capacity in two regional laboratories free of charge; it can be accessed at *malaria_rdt@who.int* and *info@finddiagnostics.org.*

Box 3: WHO selection criteria for the procurement of RDTs

Products should be selected in line with the following set of criteria, based on the results of the assessment of the WHO Malaria RDT Product Testing Programme:

(A) For the detection of *Plasmodium falciparum* (Pf) in all transmission settings the panel detection score (PDS) against Pf samples should be at least 75% at 200 parasites/µL.

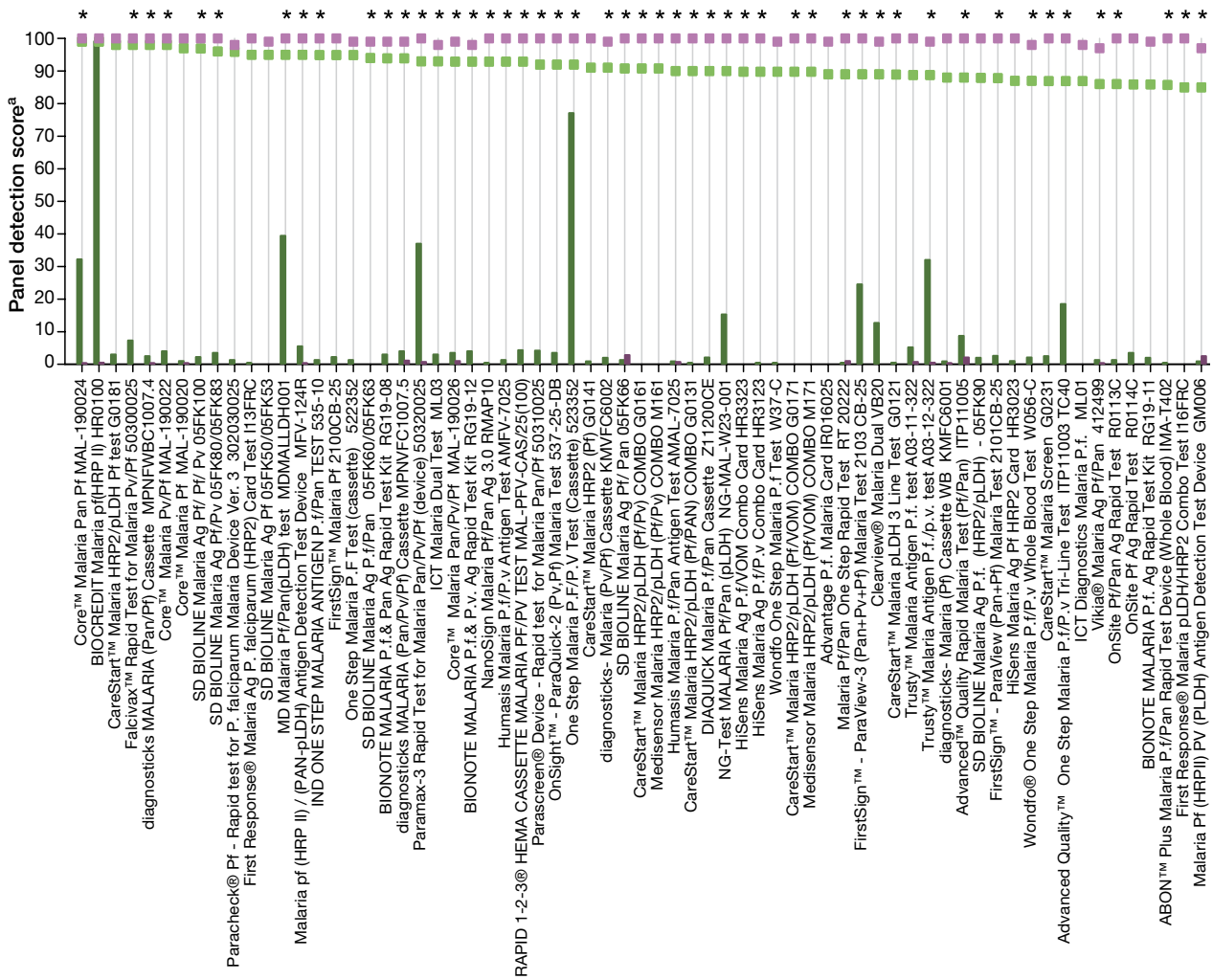
(B) For the detection of *Plasmodium vivax* (Pv) in all transmission settings the panel detection score (PDS) against Pv samples should be at least 75% at 200 parasites/µL.

(C) The false positive rate should be less than 10%.

(D) The invalid rate should be less than 5%.

Only products meeting performance criteria outlined in A,B,C and D are recommended for procurement

Figure S1: Malaria RDT performance in phase 2 of rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000–5000) parasite density (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 the 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

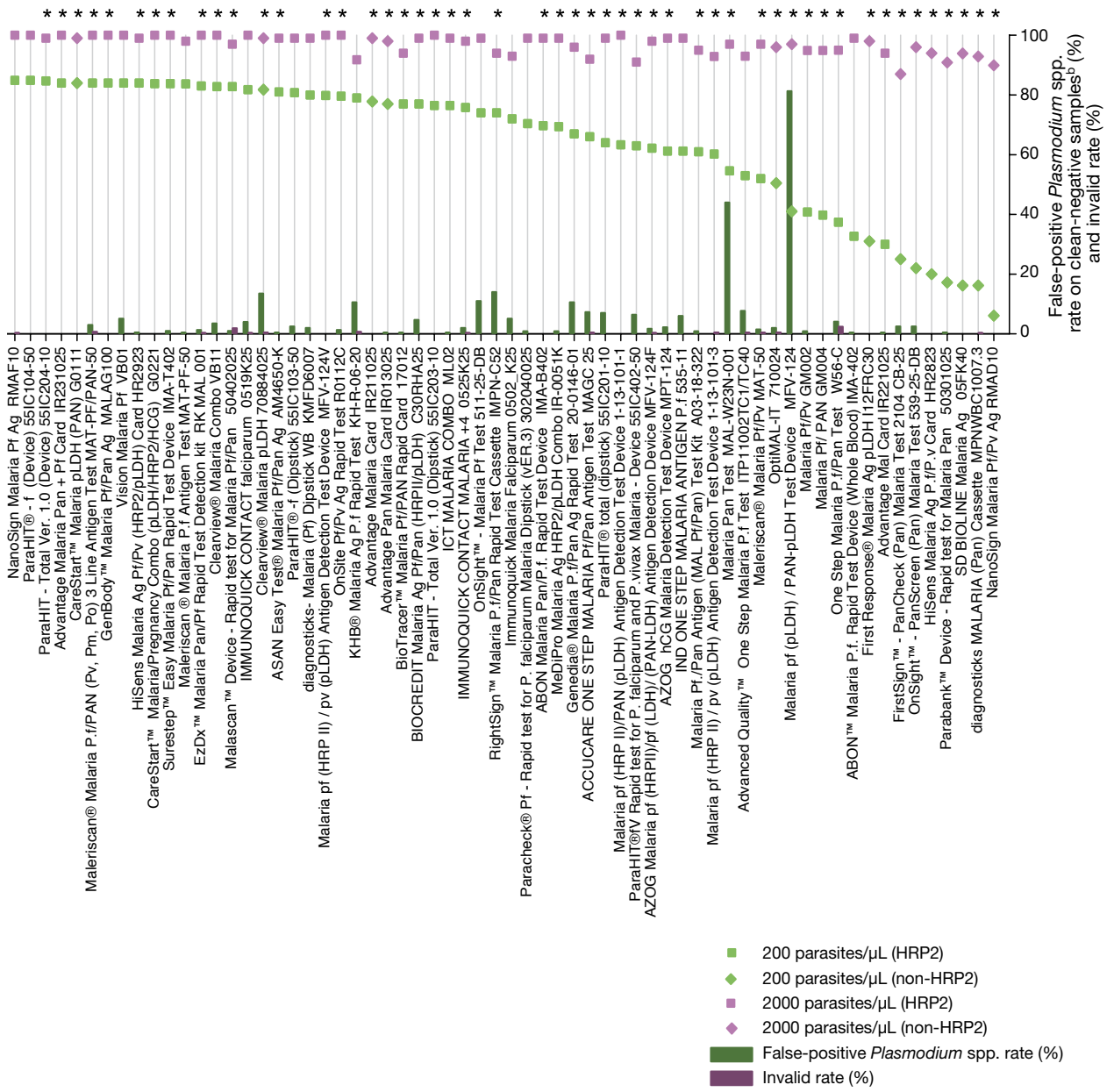
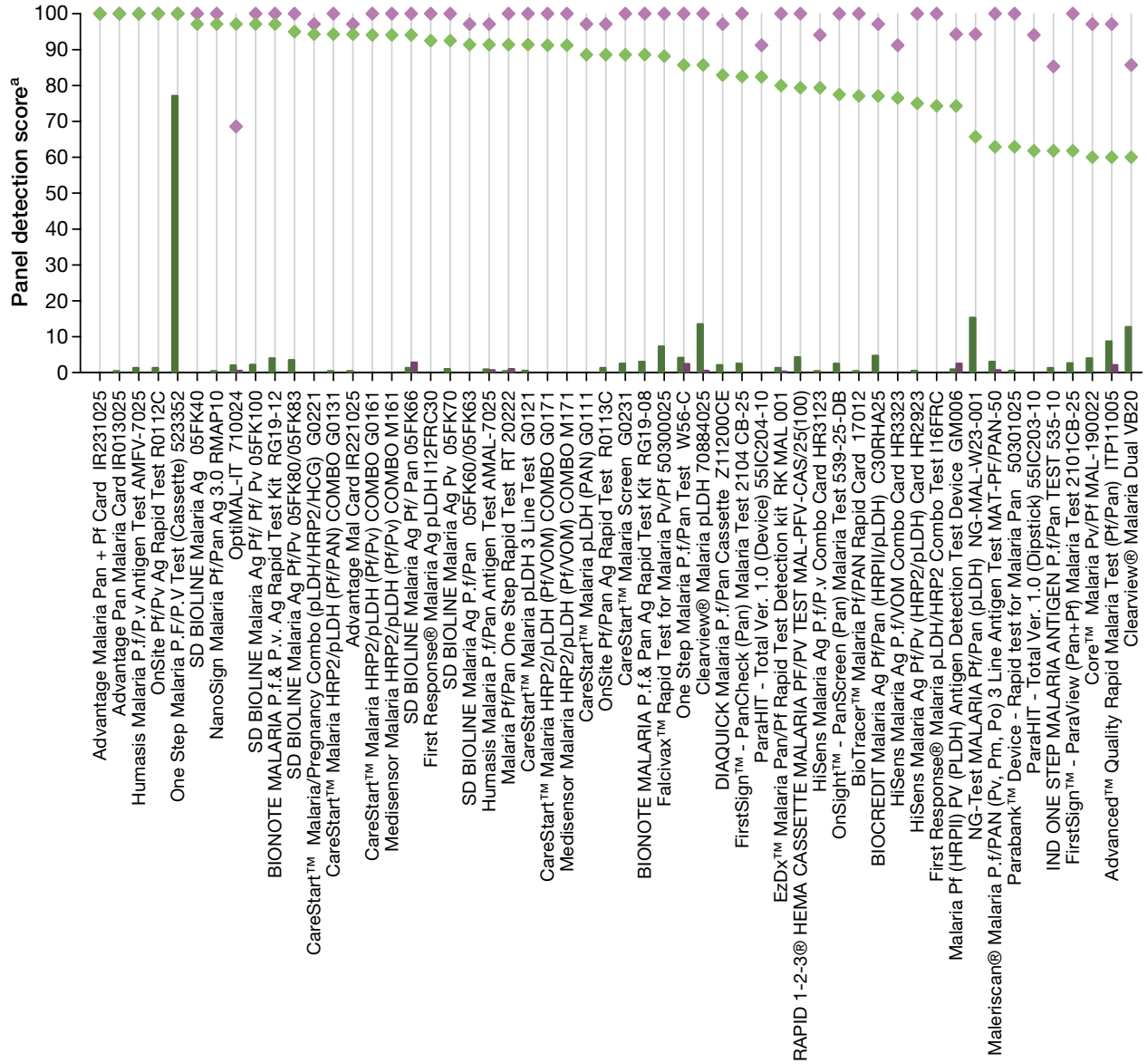

False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
0
20
40
60
80
100
NanoSign Malaria Pf Ag RMAF10
ParaHIT® -f (Device) 55IC104-50
ParaHIT - Total Ver. 1.0 (Device) 55IC204-10
Advantage Malaria Pan + Pf Card IR231025
CareStart™ Malaria pLDH (PAN) G0111
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test MAT-PF/PAN-50
GenBody™ Malaria Pf/Pan Ag MALAG100
Vision Malaria Pf VB01
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card HR2923
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) G0221
Surestep™ Easy Malaria Pf/Pan Rapid Test Device IMA-T402
Maleriscan ® Malaria P.f Antigen Test MAT-PF-50
EzDx™ Malaria Pan/Pf Rapid Test Detection kit RK MAL 001
Clearview® Malaria Combo VB11
Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
IMMUNOQUICK CONTACT falciparum 0519K25
Clearview® Malaria pLDH 70884025
ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
ParaHIT®-f (Dipstick) 55IC103-50
diagnosticks- Malaria (Pf) Dipstick WB KMFD6007
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
OnSite Pf/Pv Ag Rapid Test R0112C
KHB® Malaria Ag P.f Rapid Test KH-R-06-20
Advantage Malaria Card IR211025
Advantage Pan Malaria Card IR013025
BioTracer™ Malaria Pf/PAN Rapid Card 17012
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) C30RHA25
ParaHIT - Total Ver. 1.0 (Dipstick) 55IC203-10
ICT MALARIA COMBO ML02
IMMUNOQUICK CONTACT MALARIA +4 0525K25
OnSight™ - Malaria Pf Test 511-25-DB
RightSign™ Malaria P.f/Pan Rapid Test Cassette IMPN-C52
Immunoquick Malaria Falciparum 0502_K25
Paracheck® Pf - Rapid test for P. falciparum Malaria Dipstick (vER.3) 302040025
ABON Malaria Pan/P.f. Rapid Test Device IMA-B402
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
Genedia® Malaria P.f/Pan Ag Rapid Test 20-0146-01
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test MAGC 25
ParaHIT® total (dipstick) 55IC201-10
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device 55IC402-50
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
AZOG hCG Malaria Detection Test Device MPT-124
IND ONE STEP MALARIA ANTIGEN P.f 535-11
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit A03-18-322
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
Malaria Pan Test MAL-W23N-001
Advanced Quality™ One Step Malaria P.f Test ITP11002TC1/TC40
Maleriscan® Malaria Pf/Pv MAT-50
OptiMAL-IT 710024
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
Malaria Pf/Pv GM002
Malaria Pf/ PAN GM004
One Step Malaria P.f/Pan Test W56-C
ABON™ Malaria P.f. Rapid Test Device (Whole Blood) IMA-402
First Response® Malaria Ag pLDH I12FRC30
Advantage Mal Card IR221025
FirstSign™ - PanCheck (Pan) Malaria Test 2104 CB-25
OnSight™ - PanScreen (Pan) Malaria Test 539-25-DB
HiSens Malaria Ag P.f/P.v Card HR2823
Parabank™ Device - Rapid test for Malaria Pan 50301025
SD BIOLINE Malaria Ag 05FK40
diagnosticks MALARIA (Pan) Cassette MPNWBC1007.3
NanoSign Malaria Pf/Pv Ag RMAD10
200 parasites/µL (HRP2)
200 parasites/µL (non-HRP2)
2000 parasites/µL (HRP2)
2000 parasites/µL (non-HRP2)
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S2: Malaria RDT performance in phase 2 of rounds 2–5 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000 or 5000) parasite density (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 the minimum specified reading time, are positive.

[b] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

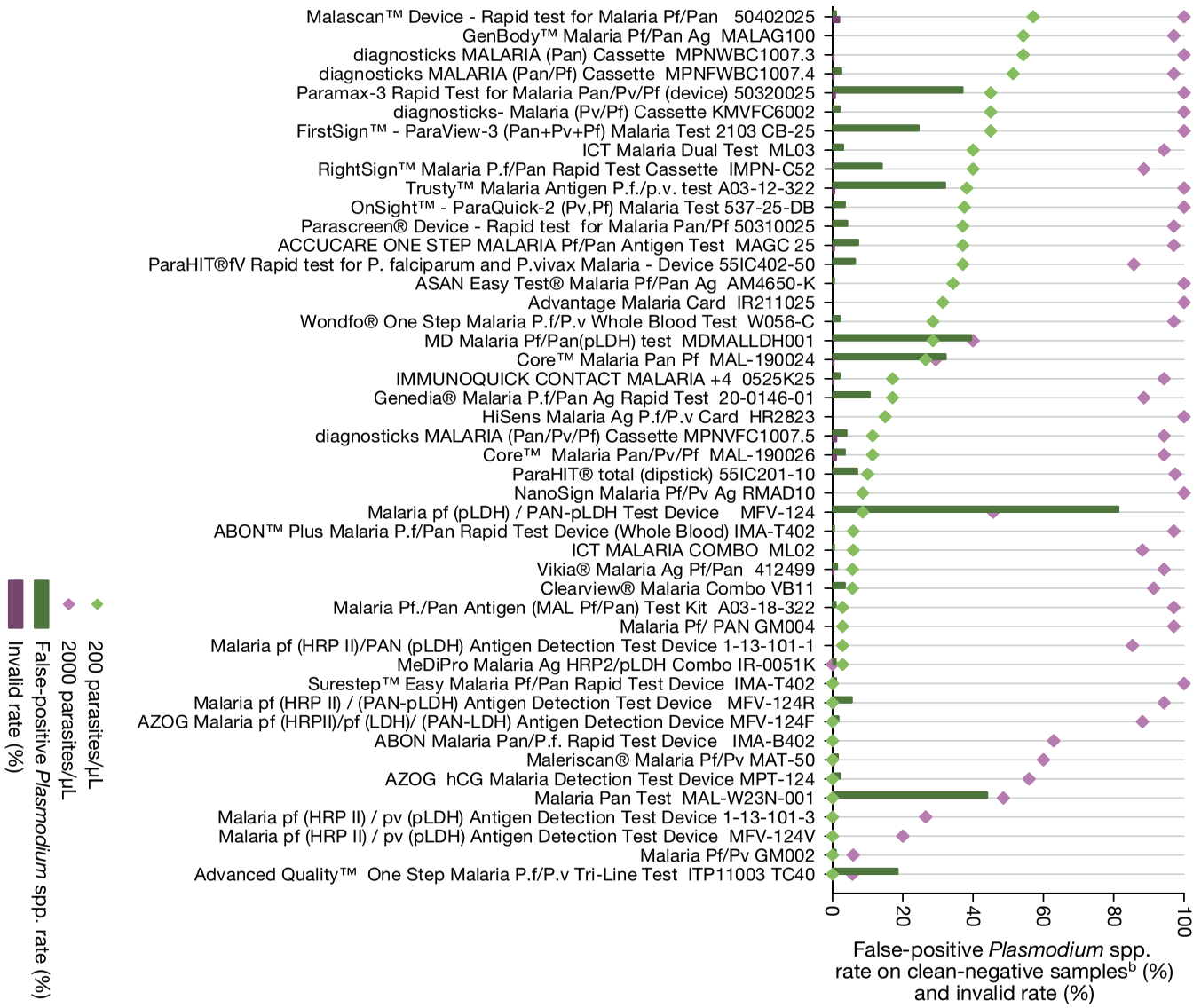
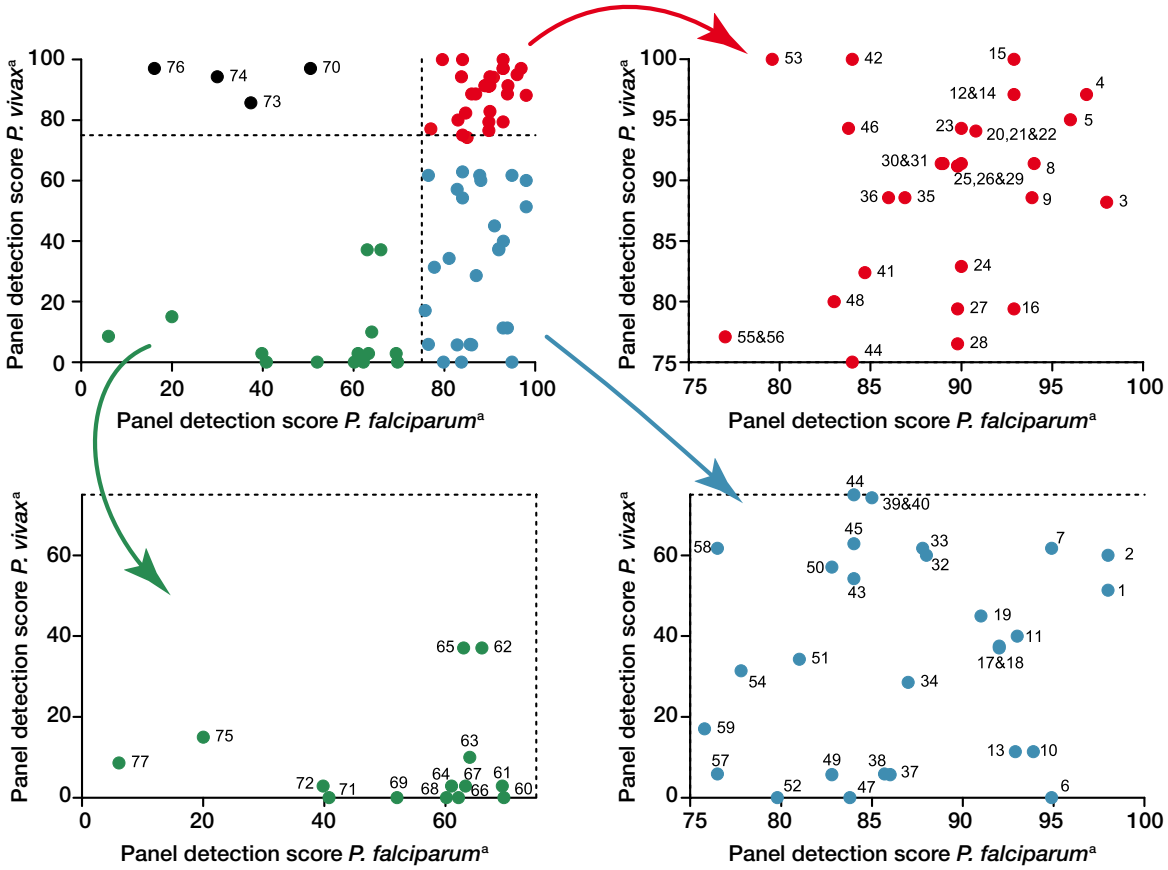

Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
GenBody™ Malaria Pf/Pan Ag MALAG100
diagnosticks MALARIA (Pan) Cassette MPNWBC1007.3
diagnosticks MALARIA (Pan/Pf) Cassette MPNFWBC1007.4
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device) 50320025
diagnosticks- Malaria (Pv/Pf) Cassette KMVFC6002
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test 2103 CB-25
ICT Malaria Dual Test ML03
RightSign™ Malaria P.f/Pan Rapid Test Cassette IMPN-C52
Trusty™ Malaria Antigen P.f./p.v. test A03-12-322
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test 537-25-DB
Parascreen® Device - Rapid test for Malaria Pan/Pf 50310025
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test MAGC 25
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device 55IC402-50
ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
Advantage Malaria Card IR211025
Wondfo® One Step Malaria P.f/P.v Whole Blood Test W056-C
MD Malaria Pf/Pan(pLDH) test MDMALLDH001
Core™ Malaria Pan Pf MAL-190024
IMMUNOQUICK CONTACT MALARIA +4 0525K25
Genedia® Malaria P.f/Pan Ag Rapid Test 20-0146-01
HiSens Malaria Ag P.f/P.v Card HR2823
diagnosticks MALARIA (Pan/Pv/Pf) Cassette MPNVFC1007.5
Core™ Malaria Pan/Pv/Pf MAL-190026
ParaHIT® total (dipstick) 55IC201-10
NanoSign Malaria Pf/Pv Ag RMAD10
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) IMA-T402
ICT MALARIA COMBO ML02
Vikia® Malaria Ag Pf/Pan 412499
Clearview® Malaria Combo VB11
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit A03-18-322
Malaria Pf/ PAN GM004
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
Surestep™ Easy Malaria Pf/Pan Rapid Test Device IMA-T402
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device MFV-124R
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
ABON Malaria Pan/P.f. Rapid Test Device IMA-B402
Maleriscan® Malaria Pf/Pv MAT-50
AZOG hCG Malaria Detection Test Device MPT-124
Malaria Pan Test MAL-W23N-001
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
Malaria Pf/Pv GM002
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test ITP11003 TC40
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µL
2000 parasites/µL
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S3: Panel detection score of malaria combination and pan-only RDTs, meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 2-5 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) parasite density (parasites/µL)



1 diagnosticks MALARIA (Pan/Pf) Cassette- MPNFWBC1007.4
2 Core™ Malaria Pv/Pf - MAL-190022
3 FalciVax™ - Rapid test for Malaria Pv/Pf - 50300025
4 SD BIOLINE Malaria Ag Pf/ Pf/ Pv - 05FK100
5 SD BIOLINE Malaria Ag Pf/Pv - 05FK80/05FK83
6 Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device - MFV-124R
7 IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST - 535-10
8 SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
9 BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
10 diagnosticks MALARIA (Pan/Pv/Pf) Cassette - MPNVFC1007.5
11 ICT Malaria Dual Test - ML03
12 BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit - RG19-12
13 Core™ Malaria Pan/Pv/Pf - MAL-190026
14 NanoSign Malaria pf/pan Ag 3.0 - RMAP10
15 Humasis Malaria P.f/P.v Antigen Test - AMFV-7025
16 RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST - MAL-PFV-CAS/25(100)
17 Parascreen® - Rapid test for Malaria Pan/Pf - 50310025
18 OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test - 537-25-DB
19 diagnosticks- Malaria (Pv/Pf) Cassette - KMVFC6002
20 CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO - G0161
21 Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO - M161
22 SD BIOLINE Malaria Ag Pf/ Pan - 05FK66
23 CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO - G0131
24 DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
25 Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
26 CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO - G0171
27 HiSens Malaria Ag P.f/P.v Combo Card - HR3123
28 HiSens Malaria Ag P.f/VOM Combo Card - HR3323
29 Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO - M171
30 Malaria Pf/Pan One Step Rapid Test - RT 20222
31 CareStart™ Malaria pLDH 3 Line Test - G0121
32 Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
33 FirstSign™ ParaView (Pan+Pf) - 2101CB-25
34 Wondfo® One Step Malaria P.f/P.v Whole Blood Test - W056-C
35 CareStart™ Malaria Screen - G0231
36 OnSite Pf/Pan Ag Rapid Test - R0113C
37 Vikia® Malaria Ag Pf/Pan - 412499
38 ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
39 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
40 Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
41 ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
42 Advantage Malaria Pan + Pf Card - IR231025
43 GenBody™Malaria Pf/Pan Ag - MALAG100
44 HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card - HR2923
45 Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
46 CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) - G0221
47 Surestep™ Easy Malaria Pf/Pan Rapid Test Device - IMA-T402
48 EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
49 Clearview® Malaria Combo - VB11
50 Malascan™ Device - Rapid test for Malaria Pf/Pan - 50402025
51 ASAN Easy Test® Malaria Pf/Pan Ag - AM4650-K
52 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
53 OnSite Pf/Pv Ag Rapid Test - R0112C
54 Advantage Malaria Card - IR211025
55 BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
56 BioTracer™ Malaria Pf/PAN Rapid Card - 17012
57 ICT MALARIA COMBO - ML02
58 ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
59 IMMUNOQUICK CONTACT MALARIA +4 - 0525K25
60 ABON Malaria Pan/P.f. Rapid Test Device - IMA-B402
61 MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
62 ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
63 ParaHIT® total (dipstick) - 55IC201-10
64 Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
65 ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-5
66 AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - MFV-124F
67 Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
68 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - MFV-124V
69 Maleriscan® Malaria Pf/Pv - MAT-50
70 OptiMAL-IT - 710024
71 Malaria Pf/Pv - GM002
72 Malaria Pf/ PAN - GM004
73 One Step Malaria P.f/Pan Test - W56-C
74 Advantage Mal Card - IR221025
75 HiSens Malaria Ag P.f/P.v Card - HR2823
76 SD BIOLINE Malaria Ag - 05FK40
77 NanoSign Malaria Pf/Pv Ag - RMAD10

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

Table S1: Product resubmissions: WHO malaria RDT product testing rounds 1–5

Manufacturer	Product name	Catalogue No.	Product re-submission Round	
			Voluntary	Compulsory
Access Bio, Inc.	CareStart™ Malaria HRP2/PLDH (Pf/Pv) COMBO	G0161	2, 4	
	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	G0171	2, 4	
	CareStart™Malaria HRP2 (Pf)	G0141	1	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	1	5
	CareStart™Malaria pLDH (PAN)	G0111	1	5
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	4, 5	
Biosynex	IMMUNOQUICK® MALARIA *falciparum*	0502_K25	1	5
AZOG	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device[a]	MFV-124R	1, 3	
	Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	3, 5	
Bhat Bio-Tech India (P) Ltd.	Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	4, 5	
Bioland	NanoSign Malaria Pf/Pan Ag	RMAP10	3, 4	
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria Pf Test (cassette)	522352	2, 3, 4	
	One Step Malaria P.F/P.V Test (Cassette)	523352	4, 5	
CTK Biotech, Inc.	Onsite Pf Ag Rapid Test	R0114C	2, 3	
	Onsite Malaria Pf/Pan Malaria Ag Rapid Test	R0113C	2, 3, 4, 5	
	Onsite Malaria Pf/Pv Ag Rapid Test	R0112C	2, 3, 4	
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024	1, 3	
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo One Step Malaria Pf/Pan Whole Blood Test	W56-C	1, 3	
	One Step Malaria P.f Test[b]	W37-C	2, 3, 4	
ICT INTERNATIONAL	ICT Malaria Combo Cassette Test	ML02	1, 3, 4	
	ICT Malaria Pf Cassette Test	ML01	1, 3	
	ICT Malaria Dual Test	ML03	3, 5	
InTec Products, Inc.	Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	1, 3	5
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	4, 5	
J.Mitra & Co. Pvt. Ltd.	Advantage Pan Malaria Card	IR013025	1	5
	Advantage Mal Card	IR221025	1	5
	Advantage P.f Malaria Card	IR016025	1	5
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for *P. falciparum* Malaria (Ver. 3)[c]	30301025	1, 3, 4	
	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver.3)[c]	30302025	1, 3, 4	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[d]	I16FRC	1, 2, 5	
	First Response Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	1	5
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	2, 5	
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40	1, 3	
	SD BIOLINE Malaria Ag Pf/Pan	05FK60/05FK63	1, 3, 5	
	SD BIOLINE Malaria Antigen	05FK50/05FK53	1	5
Unimed International Inc.	FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	2, 4	
Vision Biotech (Pty) Ltd / Orgenics (Alere Healthcare (Pty) Ltd subsidaries)	Malaria Rapid Combo/Clearview® Malaria Combo	VB11[e]	1, 3	
	Malaria Rapid Pf /Clearview ®Malaria Pf	VB01	1, 3, 5	
	Malaria Rapid Dual/Clearview® Malaria Dual Test Device	VB20[e]	1, 3, 5	
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	1, 3	
	Parabank™ Device - Rapid test for Malaria Pan	50301025	1, 3	
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025	1, 3, 4, 5	
	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025	2, 4	

[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] Ver.3 was introduced after round 1

[d] Error in WHO malaria RDT product testing: round 1 report: product code (II6FRC30) should have been (I16FRC), as in round 2

[e] New company acquisition (Alere™), therefore change in product branding and catalogue numbers; VB011 to VB11 and VB020 to VB20. Manufacturer confirmed compliance with product definition.

Table S2: Malaria RDT phase-2 performance in rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000–5000) parasite density (parasites/µL) and clean-negative samples

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)		
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples	Invalid rate (%)[l]	Round
							Pf samples	Pv samples	Pf samples	Pv samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]		
Pf only													
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	4
Advanced Quality™ One Step Malaria Pf Test[j]	ITP11002TC1/ TC40	InTec Products, Inc.	53.0	NA	93.0	NA	NA	3.6	NA	5.7	7.7 (233)	0.4	5
Advantage P.f. Malaria Card[j]	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	5
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	99.0	NA	100.0	NA	NA	97.1	NA	95.59	99.1 (231)	0.5	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	85.9	NA	99.0	NA	NA	0.0	NA	1.4	2.0	0.1	3
CareStart™ Malaria HRP2 (Pf)[j]	G0141	Access Bio, Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	5
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	98.0	NA	100.0	NA	NA	0.6	NA	1.3	3.0	0.0	2
Clearview® Malaria P.f.[j]	VB01	Vision Biotech (Pty) Ltd	83.8	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	97.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0 (198)	0.3	3
diagnosticks- Malaria (Pf) Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	88.0	NA	100.0	NA	NA	2.1	NA	1.4	0.9 (235)	0.3	5
diagnosticks- Malaria (Pf) Dipstick WB	KMFD6007	SSA Diagnostics & Biotech Systems	80.0	NA	99.0	NA	NA	2.5	NA	3.8	2.0	0.0	2
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test[j]	I13FRC	Premier Medical Corporation Ltd.	95.0	NA	100.0	NA	NA	0.7	NA	0.0	0.4	0.0	5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.47	2.2 (231)	0.2	4
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	87.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.1	2
ICT Diagnostics Malaria P.f.[j]	ML01	ICT INTERNATIONAL	86.9	NA	98.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
IMMUNOQUICK CONTACT *falciparum*	0519K25	Biosynex	81.8	NA	100.0	NA	NA	3.6 (139)	NA	1.4	4.0 (199)	0.3	3
IMMUNOQUICK® MALARIA *falciparum*[j]	0502_K25	Biosynex	72.0	NA	93.0	NA	NA	3.6	NA	4.3	5.1 (234)	0.2	5
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	61.2	NA	99.0	NA	NA	2.2	NA	14.71	6.0	0.1	4
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	79.0	NA	91.8(98)	NA	NA	11.4	NA	12.9	10.6 (235)	0.7	5
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	98.0	NA	NA	1.5	NA	0.0	0.4	0.2	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.3	3
One Step Malaria P.F Test (Cassette)[j]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0.0	NA	1.47	1.3	0.0	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	74.0	NA	99.0	NA	NA	8.1	NA	2.5	11.0	0.0	2
OnSite Pf Ag Rapid Test[j]	R0114C	CTK Biotech, Inc.	85.9	NA	100.0	NA	NA	0.7	NA	0.0	3.5	0.0	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	302030025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	NA	0.0	1.3	0.0	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0.0	NA	0.0	0.9	0.0	4
ParaHIT® - f (Device)	55IC104-50	Span Diagnostics Ltd.	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3
ParaHIT® -f (Dipstick)	55IC103-50	Span Diagnostics Ltd.	80.8	NA	99.0	NA	NA	0.0	NA	1.4	2.5	0.0	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[k]	05FK90	Standard Diagnostics Inc.	87.9	NA	100.0	NA	NA	0.0	NA	0.0	2.0	0.0	3
SD BIOLINE Malaria Ag Pf[j]	05FK50/05FK53	Standard Diagnostics, Inc.	95.0	NA	99.0	NA	NA	0.0	NA	2.9	0.0	0.0	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.94	5.2 (230)	0.7	4
Vision Malaria Pf[j]	VB01	Vision Biotech (Pty) Ltd	84.0	NA	100.0	NA	NA	2.1	NA	1.4	5.1 (235)	0.1	5
Wondfo One Step Malaria P.f Test[j]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	89.8	NA	99.0	NA	NA	0.0	NA	0.0	0.4 (231)	0.2	4
Pf and pan													
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	69.7	0.0	99.0	62.9	0.0	0.0	0.0	0.0	0.0	0.0	3
ABON™ Plus Malaria *P.f/Pan* Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0	4
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	66.0	37.1	92.0	97.1	0.3	0.0 (139)	0.0 (199)	0.0	7.3 (234)	0.4	5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	100.0	97.1	0.3 (389)	6.7 (134)	0.0 (197)	1.4	8.7 (231)	2.1	5
Advantage Mal Card[j]	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	94.0	97.1	1.5	0.7	0.5	0.0	0.4	0.0	5

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	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]		
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	100.0	100.0	3.5	0.0	0.0	0.0 (69)	0.0	0.2	5
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[k]	MFV-124F	AZOG, INC.	62.2	0.0	98.0	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	77.0	77.1	99.0	97.1	0.8	0.7	0.5 (198)	0.0	4.7	0.2	5
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
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	77.0	77.1	94.0	100.0	0.5	0.7	2.0	0.0	0.4	0.0	5
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio, Inc.	83.8	94.3	100.0	97.1	2.3	1.4 (139)	0.0 (194)	1.4	0.0	0.2	3
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO[j]	G0131	Access Bio, Inc.	90.0	94.3	100.0	100.0	1.5	0.7	0.0	0.0	0.4	0.0	5
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	88.9	91.4	100.0	100.0	1.3	0.7	6.1	0.0	0.5	0.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	86.9	88.6	100.0	100.0	1.8	2.1	0.0	0.0	2.5 (199)	0.1	3
Clearview® Malaria Combo[j]	VB11	Vision Biotech (Pty) Ltd	82.8	5.7	100.0	91.4	0.0	5.7	0.5	5.7	3.5	0.0	3
Clearview® Malaria Dual[j]	VB20	Orgenics Ltd.(IS)	89.0	60.0	99.0	85.7	0.3	12.1	0.5	7.1	12.7	0.0	5
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	100.0	29.4	0.0	33.8	0.0	42.7	32.2 (230)	0.3	4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC 1007.4	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
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	100.0	97.1	0.3	2.9	0.0	1.5 (67)	2.1	0.2	5
EzDx™ Malaria Pan/Pf Rapid Test Detection kit[j]	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	83.0	80.0	100.0	100.0	0.3	0.7 (139)	0.0	0.0	1.3 (235)	0.3	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[j]	I16FRC	Premier Medical Corporation Ltd.	85.0	74.3	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0	5
FirstSign™ ParaView (Pan+Pf)[j]	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0	4
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	100.0	97.1	0.0	0.0	0.0	0.0	0.0 (235)	0.2	5
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	96.0	88.6	0.0	13.6	0.0	7.1	10.6	0.1	5
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	20.0	15.0	94.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	84.0	75.0	99.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0	2
Humasis Malaria *P.f/Pan* Antigen Test[j]	AMAL-7025	Humasis, Co., Ltd.	90.0	91.4	100.0	97.1	0.5 (396)	0.0 (138)	0.0 (199)	1.4	0.9 (235)	0.7	5
ICT Malaria Dual Test [j]	ML03	ICT INTERNATIONAL	93.0	40.0	98.0	94.3	0.3	4.3	0.5	2.9	3.0	0.0	5
ICT MALARIA COMBO[j]	ML02	ICT INTERNATIONAL	76.5	5.9	99.0	88.2	0.5	0.7	0.0 (195)	1.5	0.4	0.1	4
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	75.8	17.1	98.0	94.3	1.8 (395)	5.1 (138)	0.0	0.0	2.0	0.3	3
IND ONE STEP MALARIA ANTIGEN *P.f/Pan* TEST	535-10	IND Diagnostics Inc.	94.9	61.8	100.0	85.3	0.0	2.2	0.0	5.9	1.3	0.0	4
Malaria 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./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	95.0	97.1	0.0 (398)	4.3	0.0 (199)	0.0	0.9	0.2	5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[j]	MFV-124R	AZOG, Inc.	95.0	0.0	100.0	94.3	0.0 (395)	7.9	8.1	0.0	5.5 (199)	0.3	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	63.3	2.9	100.0	85.3	0.0	0.0 (135)	0.0	0.0	0.0	0.1	4
Malaria pf (pLDH) / PAN-pLDH Test Device [j]	MFV-124	AZOG, Inc.	41.0	8.6	97.0	45.7	22.5	47.9	1.5	35.7	81.3 (235)	0.1	5
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics *Pvt.Ltd.*	39.8	2.9	94.9	97.1	0.3	0.7	0.0	0.0	0.0	0.0	4
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	100.0	100.0	0.0 (398)	0.7 (138)	0.0 (199)	0.0 (69)	0.4 (232)	1.0	5
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
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	95.0	28.6	100.0	40.0	0.0	38.6	0.0	40.0	39.4	0.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	99.0	0.0	0.0 (391)	0.0	0.0	1.5	0.9	0.1	4
NanoSign Malaria pf/pan Ag 3.0[j]	RMAP10	Bioland Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0	4
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
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	100.0	94.3	0.5 (399)	9.3	0.0	4.3	15.3	0.1	5

(continued)

Table S2: Malaria RDT phase-2 performance in rounds 2–5 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000–5000) parasite density (parasites/µL) and clean-negative samples *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	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]		
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
OnSite Pf/Pan Ag Rapid Test[j]	R0113C	CTK Biotech, Inc.	86.0	88.6	100.0	97.1	0.0 (399)	0.0	0.0	1.4	1.3	0.1	5
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	50.5	97.1	96.0	68.6	1.5	0.0	0.5	20.3 (69)	2.0 (198)	0.5	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	84.7	82.4	99.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	76.5	61.8	100.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	64.0	10.0	99.0	97.5	0.0	0.0	0.0	0.0	7.0	0.0	2
Parascreen® - Rapid test for Malaria Pan/Pf[j]	50310025	Zephyr Biomedicals	92.0	37.1	100.0	97.1	0.5	0.7	0.0 (199)	1.4	4.2	0.1	5
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	74.0	40.0	94.0	88.6	2.0	2.9	0.5	5.7	14.0	0.0	5
SD BIOLINE Malaria Ag *P.f/Panj*	05FK60/05FK63	Standard Diagnostics Inc.	94.0	91.4	99.0	97.1	0.8	0.7	0.5	1.4	0.0	0.0	5
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	90.8	94.1	100.0	100.0	1.0 (385)	0.0 (130)	0.0 (195)	0.0 (67)	1.3 (226)	2.8	4
SD BIOLINE Malaria Ag[j]	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	83.8	0.0	100.0	100.0	0.0	0.0	0.0	0.0	1.0	0.0	3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	97.0	94.3	0.0	0.7 (139)	0.5 (199)	0.0 (69)	1.3 (235)	0.3	5
Pf and Pv/Pvom													
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
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	81.0	34.3	99.0	100.0	16.5	0.0	85.5	0.0	0.4 (235)	0.2	5
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	92.9	97.1	98.0	100.0	0.3	0.7	1.5 (197)	0.0	4.0	0.0	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[j]	G0161	Access Bio, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[j]	G0171	Access Bio, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	98.0	60.0	100.0	97.1	0.3	0.0	0.0	0.0	4.0	0.1	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	91.0	45.0	99.0	100.0	0.3 (399)	0.6	0.0	0.0	2.0	0.1	2
FalciVax™ - Rapid test for Malaria Pv/Pf[j]	50300025	Zephyr Biomedicals	98.0	88.2	100.0	100.0	0.8	2.9	0.0	2.9	7.3	0.0	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	100.0	94.1	0.3 (391)	0.0	0.5	0.0	0.4	0.1	4
HiSens Malaria Ag *P.f/VOM* Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	100.0	91.2	0.0	0.0	0.5	0.0	0.0	0.0	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	100.0	100.0	0.5	0.7	0.5	1.5	1.3	0.0	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	92.9	26.5	0.5	0.0 (135)	3.1 (195)	1.5	0.0 (230)	0.5	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	79.8	0.0	100.0	20.0	0.0	1.4	0.0	0.0	0.0 (199)	0.1	3
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	97.0	94.3	1.5 (391)	6.5 (138)	3.6 (195)	2.9	0.9 (232)	2.5	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics *Pvt.Ltd.*	40.8	0.0	94.9	5.9	0.8	0.7	0.5	0.0	0.9	0.0	4
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test[j]	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	100.0	100.0	27.3 (399)	5.8 (139)	87.4 (199)	4.3 (69)	3.0 (232)	0.7	5
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	52.0	0.0	97.0	60.0	1.8 (399)	2.5	32.5	2.5 (79)	1.5 (199)	0.4	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4
One Step Malaria P.F/P.V Test (Cassette)[j]	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	100.0	100.0	21.5	53.6	9.0	34.3	77.1	0.0	5
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	92.0	37.5	100.0	100.0	0.5	1.9	0.0	0.0	3.5	0.1	2
OnSite Pf/Pv Ag Rapid Test[j]	R0112C	CTK Biotech, Inc.	79.6	100.0	100.0	100.0	1.5	0.0	2.0	0.0	1.3	0.0	4
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	63.0	37.1	91.0	85.7	2.0 (399)	5.7	0.5	2.9	6.4	0.1	5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	100.0	100.0	0.0	0.7	0.0	1.5	4.3	0.0	4

Table S2 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	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]		
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[k]	05FK100	Standard Diagnostics Inc.	96.9	97.1	100.0	100.0	0.3	0.0	0.5	0.0	2.2	0.0	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80/05FK83	Standard Diagnostics, Inc.	96.0	95.0	100.0	100.0	0.0	0.0 (159)	0.0 (199)	0.0	3.5	0.2	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	99.0	100.0	13.3	27.4 (135)	16.0 (194)	19.4 (67)	32.0 (231)	0.5	4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	87.0	28.6	98.0	97.1	1.5 (399)	2.9	1.5	2.9	2.1	0.1	5
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[j]	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	98.0	100.0	NA	NA	NA	NA	0.4	0.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0	99	55.9	NA	NA	NA	NA	2.2	0.2	4
CareStart™ Malaria pLDH (PAN)[j]	G0111	Access Bio, Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0	5
Clearview® Malaria pLDH[j]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	81.8	85.7	99.0	100.0	NA	NA	NA	NA	13.5	0.5	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	16.2	54.3	92.9	100.0	NA	NA	NA	NA	0.0	0.3	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	31.0	92.5	98.0	100.0	NA	NA	NA	NA	0.0	0.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	25.0	82.5	87.0	100.0	NA	NA	NA	NA	2.5	0.2	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	22.0	77.5	96.0	100.0	NA	NA	NA	NA	2.5	0.2	2
Parabank™ Device - Rapid test for Malaria Pan[j]	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	NA	NA	NA	NA	0.5	0.2	3
Pv only													
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	92.5	NA	100.0	0.3	NA	1.0	NA	1.0	0.0	2

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species
Pvom, *Plasmodium vivax, ovale* and *malariae*

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

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

[c] Round 1, n=79; round 2, n=100; round 3, n=99; round 4, n=98; round 5, n=100

[d] Round 1, n=20; round 2, n=40; round 3, n=35; round 4, n=34; round 5, n=35

[e] For combination tests, pan or Pv line, only, positive indicates a false-positive non *P. falciparum* infection (round 1 n=316; round 2, n=400; round 3, n=396; round 4, n=392; round 5, n=400)

[f] Pf line positive indicates a false-positive *P. falciparum* infection (round 1, n=80; round 2, n=160; round 3, n=140; round 4, n=136; round 5, n=140)

[g] For combination tests, pan or Pv line, only, positive indicates a false-positive non-*P. falciparum* infection (round 1, n=158; round 2, n=200; round 3, n=198; round 4, n=196; round 5, n=200)

[h] Pf line positive indicates a false-positive *P. falciparum* infection (round 1, n=40; round 2, n=80, round 3, n=70; round 4, n=68; round 5, n=70)

[i] Round 1, n=168; round 2, n=200; round 3, n=200; round 4, n=232 round 5, n=236

[j] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S1.

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

[l] Round 1, n=954; round 2, n=1240; round 3, n=1204; round 4, n=1192; Round 5, n=1214

Performance measure	Recommended WHO procurement criteria
Panel detection score for Pf and Pv 200/µL samples	≥ 75%
False-positive rates against clean-negatives	< 10%
Invalid rate	< 5% of tests conducted

Table S3: Malaria RDT rounds 2—5 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	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf only															
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	15.0	17.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Advanced Quality™ One Step Malaria Pf Test[a]	ITP11002TC1/ TC40	InTec Products, Inc.	93.3	96.7	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Advantage P.f. Malaria Card[a]	IR016025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
BIOCREDIT Malaria pf(HRP II)	HR0100	RapiGen Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	86.7	100.0	90.0	80.0	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2 (Pf)[a]	G0141	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
CareStart™ Malaria HRP2/pLDH Pf test	G0181	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
Clearview® Malaria P.f.[a]	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Core™ Malaria Pf	MAL-190020	Core Diagnostics	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pf) Cassette WB[a]	KMFC6001	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
diagnosticks- Malaria (Pf) Dipstick WB	KMFD6007	SSA Diagnostics & Biotech Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test[a]	I13FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag Pf HRP2 Card	HR3023	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	2
ICT Diagnostics Malaria P.f.[a]	ML01	ICT International	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
IMMUNOQUICK CONTACT *falciparum*	0519K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
IMMUNOQUICK® MALARIA *falciparum*[a]	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
IND ONE STEP MALARIA ANTIGEN P.f	535-11	IND Diagnostics Inc.	100.0	100.0	86.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
One Step Malaria P.F Test (Cassette)[a]	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
OnSight™ - Malaria Pf Test	511-25-DB	Amgenix International, Inc.	100.0	95.0	90.0	100.0	100.0	65.0	NA	NA	NA	NA	NA	NA	2
OnSite Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)[j]	302030025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaHIT® - f (Device)	55IC104-50	Span Diagnostics Ltd.	100.0	96.7	100.0	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	3
ParaHIT® -f (Dipstick)	55IC103-50	Span Diagnostics Ltd.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[b]	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
SD BIOLINE Malaria Ag Pf[a]	05FK50/05FK53	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Wondfo One Step Malaria P.f Test[a]	W 37-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Pf and pan															
ABON Malaria Pan/P.f. Rapid Test Device	IMA-B402	ABON Biopharm (Hangzhou) Co. Ltd.	100.0	80.0	90.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
ABON™ Plus Malaria *P.f/Pan* Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	83.3	73.3	10.0	100.0	100.0	100.0	3.3	10.0	0.0	70.0	90.0	30.0	5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	86.7	96.7	100.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5
Advantage Mal Card[a]	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5

Table S3 *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	93.3	26.7	100.0	100.0	100.0	5
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[b]	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	100.0	100.0	96.7	90.0	100.0	100.0	0.0	53.3	0.0	90.0	100.0	100.0	5
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
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	96.7	90.0	100.0	100.0	100.0	0.0	0.0	66.7	100.0	100.0	100.0	5
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[a]	G0131	Access Bio, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	93.3	86.7	53.3	100.0	100.0	100.0	5
CareStart™ Malaria pLDH 3 Line Test	G0121	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3
CareStart™ Malaria Screen	G0231	Access Bio, Inc.	100.0	100.0	93.3	100.0	100.0	100.0	100.0	100.0	93.3	100.0	100.0	100.0	3
Clearview® Malaria Comboa	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	VB20	Orgenics Ltd.(IS)	100.0	100.0	100.0	100.0	100.0	100.0	0.0	10.0	3.3	90.0	90.0	100.0	5
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	26.7	80.0	83.3	100.0	100.0	100.0	4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC 1007.4	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
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	80.0	5
EzDx™ Malaria Pan/Pf Rapid Test Detection kit[a]	RK MAL 001	Advy Chemical (Affiliate of Bharat Serums & Vaccines Ltd.)	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	3.3	100.0	100.0	100.0	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[a]	I16FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	10.0	0.0	100.0	100.0	100.0	5
FirstSign™ ParaView (Pan+Pf)[a]	2101CB-25	Unimed International Inc.	96.7	100.0	100.0	100.0	100.0	100.0	0.0	0.0	13.3	100.0	100.0	100.0	4
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	100.0	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	50.0	100.0	10.0	5
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	100.0	100.0	43.3	100.0	100.0	100.0	3.3	0.0	13.3	0.0	0.0	0.0	5
HiSens Malaria Ag P.f/P.v Card	HR2823	HBI Co., Ltd.	35.0	0.0	5.0	100.0	100.0	100.0	0.0	0.0	0.0	35.0	0.0	0.0	2
HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	95.0	100.0	100.0	100.0	2
Humasis Malaria *P.f/Pan* Antigen Test[j]	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
ICT Malaria Dual Test[a]	ML03	ICT International	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	90.0	90.0	90.0	5
ICT MALARIA COMBO[a]	ML02	ICT International	96.7	96.7	93.3	100.0	100.0	100.0	3.3	20.0	13.3	100.0	50.0	70.0	4
IMMUNOQUICK CONTACT MALARIA +4	0525K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	50.0	50.0	100.0	3
IND ONE STEP MALARIA ANTIGEN *P.f/Pan* TEST	535-10	IND Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	20.0	3.3	33.3	100.0	100.0	100.0	4
Malaria 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./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	10.0	6.7	0.0	100.0	100.0	100.0	10.0	3.3	0.0	100.0	100.0	90.0	5
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device[a]	MFV-124R	AZOG, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	100.0	96.7	96.7	100.0	100.0	100.0	16.6	0.0	0.0	90.0	40.0	50.0	4
Malaria pf (pLDH) / PAN-pLDH Test Device a	MFV-124	AZOG, Inc.	46.7	56.7	66.7	100.0	100.0	100.0	13.3	93.3	100.0	60.0	100.0	100.0	5
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics *Pvt.Ltd.*	56.7	23.3	26.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	90.0	50.0	4
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	96.7	100.0	90.0	100.0	0.0	0.0	0.0	100.0	90.0	100.0	5
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
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
NanoSign Malaria pf/pan Ag 3.0[a]	RMAP10	Bioland Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
NanoSign Malaria Pf/Pv Ag	RMAD10	Bioland, Ltd	0.0	0.0	0.0	20.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	5
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

(continued)

Table S3: Malaria RDT rounds 2—5 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 *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage 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			
OnSite Pf/Pan Ag Rapid Test[a]	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	3.3	90.0	100.0	100.0	5
OptiMAL-IT	710024	Diamed - A Division of Bio-Rad	0.0	0.0	0.0	100.0	90.0	0.0	0.0	0.0	0.0	100.0	90.0	0.0	3
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd.	100.0	93.3	46.7	100.0	100.0	60.0	50.0	0.0	0.0	100.0	90.0	0.0	4
ParaHIT® total (dipstick)	55IC201-10	Span Diagnostics Ltd	55.0	85.0	55.0	100.0	100.0	95.0	10.0	0.0	0.0	50.0	45.0	70.0	2
Parascreen® - Rapid test for Malaria Pan/Pf[a]	50310025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	10.0	3.3	13.3	100.0	100.0	100.0	5
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	20.0	100.0	100.0	60.0	100.0	5
SD BIOLINE Malaria Ag *P.f/Pana*	05FK60/05FK63	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
SD BIOLINE Malaria Ag Pf/ Pan	05FK66	Standard Diagnostics Inc.	96.7	96.7	100.0	90.0	100.0	100.0	16.6	10.0	0.0	90.0	100.0	100.0	4
SD BIOLINE Malaria Ag[a]	05FK40	Standard Diagnostics Inc.	0.0	0.0	0.0	100.0	80.0	90.0	0.0	0.0	0.0	80.0	20.0	90.0	3
Surestep™ Easy Malaria Pf/Pan Rapid Test Device	IMA-T402	ACON Biotech (Hangzhou) Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	60.0	0.0	5
Pf and Pv/Pvom															
Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test	ITP11003 TC40	InTec Products, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Advantage Malaria Card	IR211025	J. Mitra & Co. Pvt. Ltd.	100.0	96.7	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	96.7	63.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit	RG19-12	Bionote,Inc.	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO[a]	G0161	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO[a]	G0171	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Core™ Malaria Pv/Pf	MAL-190022	Core Diagnostics	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	SSA Diagnostics & Biotech Systems	100.0	95.0	95.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
FalciVax™ - Rapid test for Malaria Pv/Pf[a]	50300025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag *P.f/VOM* Combo Card	HR3323	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	100.0	100.0	100.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	AZOG, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	83.3	90.0	83.3	100.0	90.0	70.0	NA	NA	NA	NA	NA	NA	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics *Pvt.Ltd.*	40.0	33.3	40.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Maleriscan® Malaria Pf/Pv	MAT-50	Bhat Bio-Tech India (P) Ltd	100.0	60.0	30.0	100.0	90.0	95.0	NA	NA	NA	NA	NA	NA	2
Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171	Medisensor, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
One Step Malaria P.F/P.V Test (Cassette)[a]	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	Amgenix International, Inc.	100.0	100.0	100.0	100.0	100.0	85.0	NA	NA	NA	NA	NA	NA	2
OnSite Pf/Pv Ag Rapid Test[a]	R0112C	CTK Biotech, Inc.	100.0	100.0	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	100.0	96.7	96.7	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	5
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/ Pf/ Pv[b]	05FK100	Standard Diagnostics Inc.	100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
SD BIOLINE Malaria Ag Pf/Pv	05FK80/05FK83	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	95.0	NA	NA	NA	NA	NA	NA	2
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	100.0	100.0	36.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	100.0	96.7	93.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5

Table S3 *(continued)*

Product	Catalogue number	Manufacturer	Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (Pf line)			Percentage positive test results for *P. falciparum* (pan line)			Percentage positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf, Pv and pan															
Core™ Malaria Pan/Pv/Pf	MAL-190026	Core Diagnostics	100.0	100.0	100.0	100.0	90.0	100.0	0.0	0.0	0.0	80.0	50.0	70.0	3
diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	SSA Diagnostics & Biotech Systems	96.7	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	70.0	0.0	50.0	3
FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	60.0	50.0	15.0	100.0	90.0	100.0	2
Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	25.0	30.0	100.0	95.0	100.0	2
Pan only															
Advantage Pan Malaria Card[a]	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	36.7	66.7	60.0	100.0	100.0	90.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	4
CareStart™ Malaria pLDH (PAN)[a]	G0111	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5
Clearview® Malaria pLDH[a]	70884025	Orgenics Ltd. (Inverness Medical Innovations)	NA	NA	NA	NA	NA	NA	96.7	93.3	100.0	100.0	100.0	100.0	3
diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	80.0	100.0	80.0	3
First Response® Malaria Ag pLDH	I12FRC30	Premier Medical Corporation Ltd.	NA	NA	NA	NA	NA	NA	50.0	80.0	55.0	100.0	100.0	100.0	2
FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	Unimed International Inc.	NA	NA	NA	NA	NA	NA	25.0	5.0	10.0	100.0	100.0	100.0	2
OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	Amgenix International, Inc.	NA	NA	NA	NA	NA	NA	5.0	35.0	15.0	100.0	100.0	100.0	2
Parabank™ Device - Rapid test for Malaria Pan[a]	50301025	Zephyr Biomedical Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	90.0	100.0	100.0	3
Pv only															
SD BIOLINE Malaria Ag Pv	05FK70	Standard Diagnostics, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

Indicates results for those products that meet all WHO recommended procurement criteria

[a] Product resubmission, results from most recent round of testing replace previous results. Refer to Table S1.

[b] Results presented in the table are based on stability of a Pf test line (either Pf-HRP2 or Pf-pLDH). Results based on stability of individual test lines is presented in the following table:

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

2. WHO MALARIA RDT PRODUCT TESTING: ROUND 5: EXECUTIVE SUMMARY

2.1. Introduction

WHO estimates that half the world's population is at risk of malaria. In 2012, there were an estimated 207 million cases (with an uncertainty range of 135 million to 287 million) and an estimated 627 000 deaths (with an uncertainty range of 473 000 to 789 000). Approximately 90% of all malaria deaths occur in sub-Saharan Africa, and 77% occur in children under 5 years. Malaria remains endemic in 104 countries, and, while parasite-based diagnosis is increasing, most suspected cases of malaria are still not properly confirmed, resulting in over-use of antimalarial drugs and poor disease monitoring (*1*).

WHO recommends that malaria case management be based on parasite diagnosis in all cases (*2*). The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained.The data generated by the WHO and FIND programme to evaluate and compare the performance of commercially available malaria RDTs are guiding procurement decisions, which, in turn, have shifted markets towards better performing tests and helped to improve the quality of manufacturing. The results of WHO malaria RDT product testing form the basis of procurement criteria and constitute the laboratory evaluation component of WHO prequalification for malaria RDTs. This report provides the results of round 5 of product testing, performed at the CDC in 2013, with data on the performance of 42 products. This evaluation adds to the evaluations of rounds 1–4 (*3*–*6*), which should be considered as a single evaluation, except that the results for products tested in previous rounds that were resubmitted for testing replace those reported previously. From round to round, the evaluation panels are essentially the same (Annex S1), and the same or slightly modified testing protocols are followed. This report extends the data from previous rounds and therefore increases the number of RDTs available for procurement for which detailed, comparative data are available on aspects of performance relevant to field use. The report provides updated data on the performance of products at least every 5 years, as a result of implementation of the compulsory resubmission policy. Products that are not resubmitted are deleted from the summary results of WHO product testing and are not eligible for WHO procurement.

2.2. The WHO product testing programme

Product testing is part of the WHO-FIND malaria RDT evaluation programme, which develops methods for evaluation and provides data on antigen-detecting malaria RDTs. The programme is a collaboration among many institutions in malaria-endemic and non-endemic countries, with a global specimen bank and testing performed at the CDC (Fig. 2).

All companies that manufacture according to ISO 13485:2003 quality system standards were invited to submit one test for evaluation in the programme, except manufacturers who were required to submit additional products under the new compulsory resubmission rules. The 42 products from 34 manufacturers[1] were evaluated with prepared blood panels of cultured *P. falciparum* parasites, patient-derived wild-type *P. falciparum* and *P. vivax* parasites, and a parasite-negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a descriptive assessment of ease of use was recorded. As for previous rounds, RDTs are grouped in the tables and figures into those that detect *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 23 products that had been tested in previous rounds comprised 10 compulsory resubmissions and 13 voluntary resubmissions (Table 1a,b).

The aim of the evaluation is to provide comparative data on the performance of the submitted production lots of each product against samples containing low (200 parasites/µL) and high densities (2000 or 5000 parasites/µL) of *P. falciparum* or *P. vivax*. Because the concentration of target antigens in samples with the same parasite density is variable, the evaluation panel selection process is adjusted to ensure that there is no statistically significant difference in mean or median antigen concentrations for HRP2, aldolase and pLDH between panels used in different rounds of testing (Annex S1, Table 3).

The data in this report are used to guide procurement decisions by WHO, other United Nations agencies and national governments. Product testing is part of a continuing programme to improve the quality of RDTs that are used and to support widespread, reliable malaria diagnosis in areas where malaria is prevalent. A sixth round of product testing began in June 2014, and the results will be published in 2015.

[1] Several manufacturers are subsidiaries of Alere™ .

2.3. Results of the evaluation

The results (summarized in Tables 4–6 and Figs 10, 11, 14 and 15) provide a comparison of two lots of products against a panel of parasite samples diluted to a low parasite density (200 parasites/µL), considered to be close to the threshold that tests must detect in order reliably to identify clinical malaria in many settings (*9*), and a higher parasite density (2000 or 5000 parasites/µL).

For the purposes of this report, the main measure of performance is the PDS, the percentage of malaria samples in a panel that give a positive result in 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 clinical sensitivity or of the positivity rate against the panel but rather a combined measure of positivity rate and inter-test and inter-lot consistency.

As for products evaluated in previous rounds of product testing, the PDS varies widely, some products showing high performance in detecting parasites, in thermal stability and other performance measures. Overall, there is no obvious trade-off between the PDS (or positivity rate) and the false-positive rate, which are surrogates for sensitivity and specificity in the field, respectively. Furthermore, a number of tests showed good outcomes for both these indicators.

The basis for *P. falciparum* detection by combination RDTs (*P. falciparum*/pan, *P. falciparum*/*P. vivax*, *P. falciparum*/*P. vivax*, *ovale* and *malariae*), particularly in samples with low parasite density, is predominantly detection of HRP2 and not pLDH. In other words, mainly the HRP2 test band reacts with *P. falciparum*-containing samples, probably reflecting poorer affinity of the monoclonal pLDH antibodies on the pLDH test band and not HRP2 persistent antigenaemia, as all samples are known to contain *P. falciparum* (and pLDH).

In round 5, the results for 80% (8/10) and 75% (3/4) of the compulsorily retested products were within 10% of the initial test for detection of *P. falciparum* and *P. vivax* at 200 parasites/µL. Most of the differences detected were decreases in performance in comparison with previous testing. Among the voluntary resubmissions, 77% (10/13) and 73% (8/11) of products showed better detection of *P. falciparum* and *P. vivax* at 200 parasites/µL, respectively. Detection of *P. falciparum* improved by 11% on average, while the mean improvement in *P. vivax* detection was 29%. Two products, however, showed significantly increased (> 75%) false-positive rates in round 5. In combination tests, there was no significant correlation between improvements in *P. falciparum* and *P. vivax* detection, suggesting that changes in detection of these two parasite species occurred independently of each other.

Several products had very high false-positive rates for *P. falciparum* against clean negatives, and, as previously reported, high false-positive rates were seen with several products against blood samples containing specific immunological abnormalities (e.g. rheumatoid factor, anti-mouse antibodies) (Table A4.9). The number of samples evaluated was, however, small, and the clinical significance of these results is limited, although they may be important in certain populations with very low parasite prevalence.

Some products showed variation in performance between the two lots evaluated, confirming the advisability of lot-testing before field use.

Heat (thermal) stability varied widely, some products retaining high positivity rates after 2 months' storage at 45 °C and 75% humidity. For many products, pan-line performance at baseline and post-heat stress for detection of the *P. falciparum* isolate were poor and nearly universally poor against low parasite density samples, making true stability difficult to assess.

The majority of the products evaluated showed a variable frequency of anomalies that could interfere with test interpretation, the most common being a red background and incomplete clearing (Table 8).

The clinical sensitivity of an RDT, i.e. the proportion of people known to have the disease who test positive for it, is highly dependent on local conditions, including the parasite density in the target population, and therefore varies among populations with differing levels of transmission. 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 PDS 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. For areas where significant non-expression of HRP2 is known, the results of HRP2-detecting tests in this report should not be considered to predict sensitivity in the field. Only tests targeting *P. falciparum* by detection of pLDH or aldolase should be considered.

Heat stability (summarized in Table 6) is vital to maintaining the sensitivity of a test in the field. For procurement, therefore, the results for stability should be used to ensure that products to be used in areas with high temperatures during transport and storage have demonstrated good stability in the product testing programme. The requirements vary by country; for example, if tests are to be used in areas where the temperature rarely rises above 30 °C, stability at high temperatures is less important.

The requirements for ease of use depend on the extent of training and the work environment of users. Particularly in primary health care settings, the simpler the test, the easier it should be to avoid errors in preparation and interpretation.

2.4. Use of the results

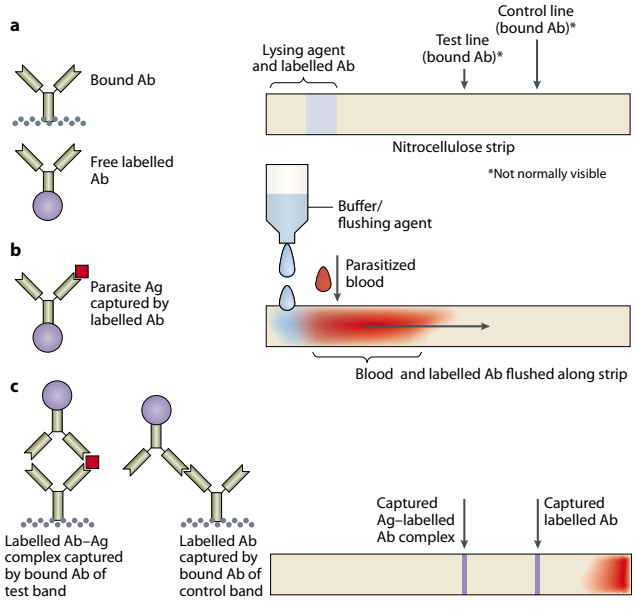
Box 3 outlines WHO's minimum criteria for selecting RDTs, and tabular results in Tables S2 and 5 are colour-coded to reflect achievement of these requirements, and a web-based tool that allows filtering of product testing results by various parameters to assist in selecting products with the performance characteristics most suitable for a country's health programme is available and maintained by FIND (*12*). Annex S3 provides a step-by-step approach to selecting an RDT, taking into consideration local conditions of malaria transmission and illness (e.g. *Plasmodium* species, target antigen variation, parasite densities, climate), and other important considerations, including ease of use in the field, for training and retraining and lot testing. RDTs must not be procured without programme and infrastructure preparation for proper use, including supply chain management, training in test usage and disposal, and training in patient management in response to results. Comprehensive guidance on several aspects of procurement can be found in *Good practices for selecting and procuring rapid diagnostic tests for malaria* and guidance on implementation in *Universal access to malaria diagnosis* (*13*, *14*).

3. BACKGROUND

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

Despite WHO's recommendation for a parasitologically confirmed diagnosis of malaria infection before treatment in all cases (*2*), diagnoses are still often made on clinical grounds (*9*), whereas in most endemic areas malaria accounts for a minority of cases of "malaria-like" febrile illness. Microscopy has been the cornerstone of diagnosis and is recommended for malaria diagnosis when its quality can be maintained; however, the need for trained personnel and adequate reagents and equipment limits its availability and accessibility in malaria-endemic areas. Rapid, accurate, accessible diagnostic tools are increasingly required as programmes extend parasite-based diagnosis and the prevalence of malaria decreases. RDTs to detect *Plasmodium*-specific antigens (proteins) in whole blood of infected people have emerged as an attractive alternative to microscopy. The currently available RDTs come in various formats (dipstick, cassette or hybrids) and contain antibodies bound to specific antigens, such as HRP2 specific to *P. falciparum*, pan-specific and species-specific pLDH or aldolase specific to all the major *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale)* (Fig. 1).

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



Mode of action of common malaria RDT format:

(a) Dye-labelled antibody (Ab), specific for the 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 (Ag), 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 labelled antibody and are drawn up the strip across the lines of bound antibody.

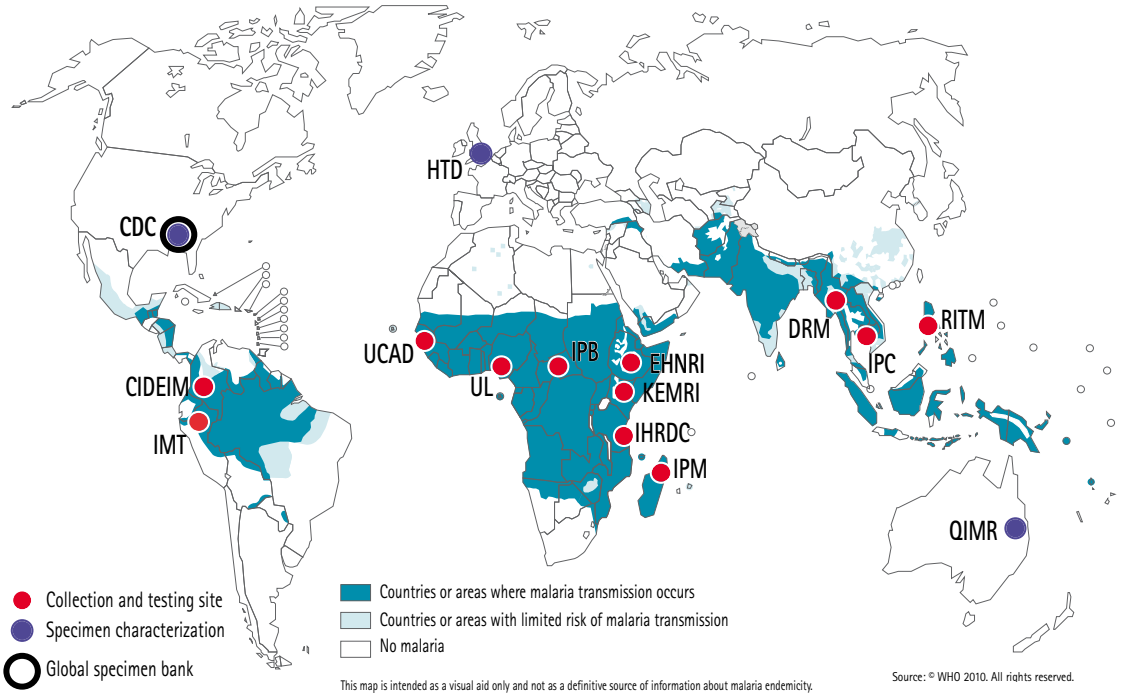
(c) If antigen is present, some labelled antibody will be trapped on the test line. Other labelled antibody is trapped on the control line.

To be widely useful, an RDT must be highly sensitive to ensure detection of all clinically significant malaria infections, highly specific to allow monitoring of low malaria prevalence and appropriate management of non-malarial fevers and highly stable to allow transport and storage in ambient conditions in malaria-endemic areas. Published field trials of RDTs show highly variable performance, probably due to poor manufacturing quality, incorrect storage and handling, poor preparation and interpretation, and sometimes poor study methods, analysis and reporting (*15–23*). 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 (*9*).

The number of RDTs available on the market has grown rapidly since their introduction in the late 1990s, with an estimated 60 brands and over 200 tests commercially available today and 205 million tests or more procured in 2012 (*1*). Regulatory control of diagnostics is, however, often weak, and procurement agencies have had considerable difficulty in selecting appropriate RDTs and ensuring their quality. In view of the inconsistency in the results of field studies and the inherent difficulties in assessing large numbers of products in a standardized way in field trials, WHO and partners embarked on a programme to evaluate RDTs for malaria in 2002 to ensure standardized assessment of performance and to guide procurement decisions and regulatory mechanisms. Between 2003 and mid-2012, the programme was managed by WHO and TDR in partnership with FIND. After TDR withdrew its involvement in 2012, the WHO Global Malaria Programme assumed a coordinating role. A steering committee oversees the development of and modifications to standard operating procedures (*24,25*). A network of specimen collection sites has been established to provide specimens for a global bank at the CDC and to facilitate local quality control (Fig. 2).

The reports of the previous four rounds of product testing have been released annually since 2009 (*3–6*). This fifth report adds data on the performance of 19 new products and updated data on 23 resubmitted RDTs. Testing for round 5 was conducted against an evaluation panel with similar characteristics to previous panels in terms of overall antigen concentration, parasite origin and parasite-negative blood samples (Annex S1). Most panel samples were retained from previous rounds, with 36 of 100 *P. falciparum*, 7 of 35 *P. vivax* and 48 of 100 negative samples replaced (new) in round 5.

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



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); IHRDC, Ifakara Health Research and Development Center (Bagamoyo, 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, Philippines); UCAD, Université Cheikh Anta DIOP (Dakar, Senegal); UL, University of Lagos (Lagos, Nigeria).

4. OBJECTIVE

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

5. MATERIALS AND METHODS

5.1. Test selection

In August 2012, the WHO-FIND malaria RDT evaluation programme issued a call for expressions of interest to manufacturers of malaria RDTs with information on the requirements for submission of a product to round 5 and the conditions for participation in the evaluation programme (*26*). Manufacturers of products that had not been retested since round 1 were informed of a new requirement to resubmit products within less than 5 years or to have these products and their performance characteristics removed from the summary results document, which is a compilation of the results of all previous rounds of testing. Other standard requirements included valid ISO 13485:2003 certification from all manufacturing sites, a supply of sufficient quantities of products (1100 tests from each of two lots),[1] compliance with the product definition[2] and deadlines for document submission.

Thirty-nine manufacturers, proposing 99 products, responded to the call. In order to keep to the schedule and budget and to accommodate 10 compulsory product resubmissions, manufacturers were asked to limit their voluntary submissions to one product. Finally, 42 products were tested in round 5 (Table 1a). Catalogue numbers and verification with

[1] Manufacturers were requested to supply an additional 500 RDTs per lot voluntarily to support the WHO-FIND evaluation of malaria recombinant antigens.

[2] A working definition of a product can be found in Annex 2 (*http://www2.wpro.who.int/NR/rdonlyres/EEF2F4B0-5863-438A-8442-8F8CC1AA7F8B/0/EOIAnnex1_2_3_Round5_version21.docx*, accessed 23 May 2014).

Table 1a: Manufacturers and products accepted into round 5 of WHO malaria RDT product testing Programme

Manufacturer	Product name	Catalogue number[a]	Target antigens	
Access Bio. Inc.	CareStart™ Malaria pLDH (PAN)[b]	G0111/G0111-ET	pan-pLDH	–
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo[b]	G0131/G0131-ET	pan-pLDH	HRP2
	CareStart™ Malaria HRP2 (Pf)[b]	G0141/G0141-ET	HRP2	–
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit[d]	RK MAL 001	pan-pLDH	HRP2
Artron Laboratories Inc.	Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	pan-pLDH	HRP2
ASAN Pharmaceutical Co., Ltd	ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	Pvom-pLDH	HRP2
AZOG, INC.	Malaria pf-LDH/PAN-LDH Antigen Test Device[d]	MFV-124	pan-pLDH	PfpLDH
Bhat Bio-Tech India (P) Ltd.	Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test[d]	MAT-PF/PAN-50	Pvom-pLDH	HRP2
Bio Focus Co., Ltd.	BioTracer™ Malaria Pf/PAN Rapid Card	17012	pan-pLDH	HRP2
BIOSYNEX	IMMUNOQUICK® MALARIA *falciparum*	0502_K25	HRP2	–
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F/P.V Test[d]	523352	Pv-pLDH	HRP2

Table 1a: *(continued)*

Manufacturer	Product name	Catalogue number[a]	Target antigens	
CTK Biotech Inc.	OnSite Pf/Pan Ag Rapid Test[d]	R0113C	HRP2	pan-pLDH
DIALAB GmbH	DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	pan-pLDH	HRP2
GenBody Inc.	GenBody™ Malaria Pf/Pan Ag	MALAG100	pan-pLDH	HRP2
Genomix Molecular Diagnostics Pvt. Ltd.	Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	HRP2	Pv-pLDH
Green Cross Medical Science Corp. (Korea)	Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	pan-pLDH	HRP2
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Pv-pLDH	HRP2
Hangzhou Biotest Biotech Co. Ltd.	RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	aldolase	HRP2
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test[d]	AMAL-7025	pan-pLDH	HRP2
ICT INTERNATIONAL	ICT Malaria Dual Test[d]	ML03	HRP2	pan-pLDH
IMACCESS S.A.S	Vikia® Malaria Ag Pf/Pan	412499	HRP2	aldolase
InTec Products, Inc.	Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	pan-pLDH	HRP2
	Advanced Quality™ One Step Malaria Pf Test[b]	ITP11002TC1/TC40	HRP2	–
J. Mitra & Co. Pvt. Ltd.	Advantage Mal Card[b]	IR221025	pan-pLDH	Pf-pLDH
	Advantage Malaria Pan + Pf Card	IR231025	pan-pLDH	HRP2
	Advantage Pan Malaria Card[b]	IR013025	pan-pLDH	–
	Avantage P.f Malaria Card[b]	IR016025	HRP2	–
LAB-CARE Diagnostics (India) PVT. LTD.	ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	pan-pLDH	HRP2
Medical Diagnostech (Pty) Ltd	MD Malaria Pf/Pan-pLDH test	MDMALLDH001	HRP2	pan-pLDH
SARL NG Biotech, Z.A.	NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	HRP2	pan-pLDH
Premier Medical Corporation	First Response® Malaria Ag *P. falciparum* (HRP2) Card Test[b]	I13FRC	HRP2	–
	First Response® Malaria Ag. pLDH/HRP2 Combo Card Test[d]	I16FRC	pan-pLDH	HRP2
RapiGEN INC.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	pan-pLDH	HRP2
Shanghai Kehua Bio-engineering Co.,Ltd.	KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	HRP2	–
Span Diagnostics Ltd.	ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Pv-pLDH	HRP2
SSA Diagnostics & Biotech Systems	diagnosticks-Malaria (Pf) Rapid Diagnostic Test[d]	KMFC6001	HRP2	–
Standard Diagnostics Inc.c	SD BIOLINE Malaria Antigen Pf[b]	05FK50/05FK53	HRP2	–
	SD BIOLINE Malaria Antigen Pf/Pan[d]	05FK60	pan-pLDH	HRP2
Orgenics Ltd.(IS)c	Clearview® Malaria Dual[d]	VB20	HRP2	pan-pLDH
Vision Biotech (Pty) Ltdc	Vision Malaria Pf[d]	VB01	HRP2	–
Zephyr Biomedicals	Parascreen® Rapid test for malaria Pan/Pf[d]	50310025	pan-pLDH	HRP2
Zhejiang Orient Gene Biotech Co., Ltd.	Malaria Pf/Pan One Step Rapid Test	RT 20222	HRP2	pan-pLDH

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

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

[b] Indicates products submitted for compulsory retesting in round 5

[c] Alere subsidaries

[d] These products have been submitted voluntarily to previous rounds of WHO malaria RDT product testing (round 1-4). For details on all product resubmissions refer to Table S1.

manufacturers showed that 23 of the 42 products (55%) had been submitted previously to one or more rounds, including 10 (45%) scheduled for compulsory resubmission (Table1b). All the products met the minimum performance requirements[1] in the initial evaluation against the *P. falciparum* culture-derived panel (phase 1) and were therefore evaluated fully.

Of the 42 products that were fully evaluated, 9 are designed to detect *P. falciparum* alone, 31 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria and from *P. falciparum* and *P. vivax* or *P. vivax, ovale, malariae*, and 2 to detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them. Annexes 1 and 2 give a comprehensive overview of the product characteristics.

5.2. The product testing protocol

The testing process is outlined in Fig. 3 and in the *Methods manual for product testing of malaria rapid diagnostic tests, version 5 (24)*. In brief, RDTs from each of two lots of each product were evaluated against a panel of parasite-positive and parasite-negative cryopreserved blood samples and a panel of parasite-negative samples. Both lots were also tested for heat (thermal) stability, evaluated after 2 months' storage at 4 °C, 35 °C and 45 °C. An ease-of-use description was completed in a standard assessment format, and common RDT anomalies were recorded.

The testing and all the results were monitored by the WHO-FIND steering committee, and manufacturers were given 30 days to comment on the results for individual products before publication.

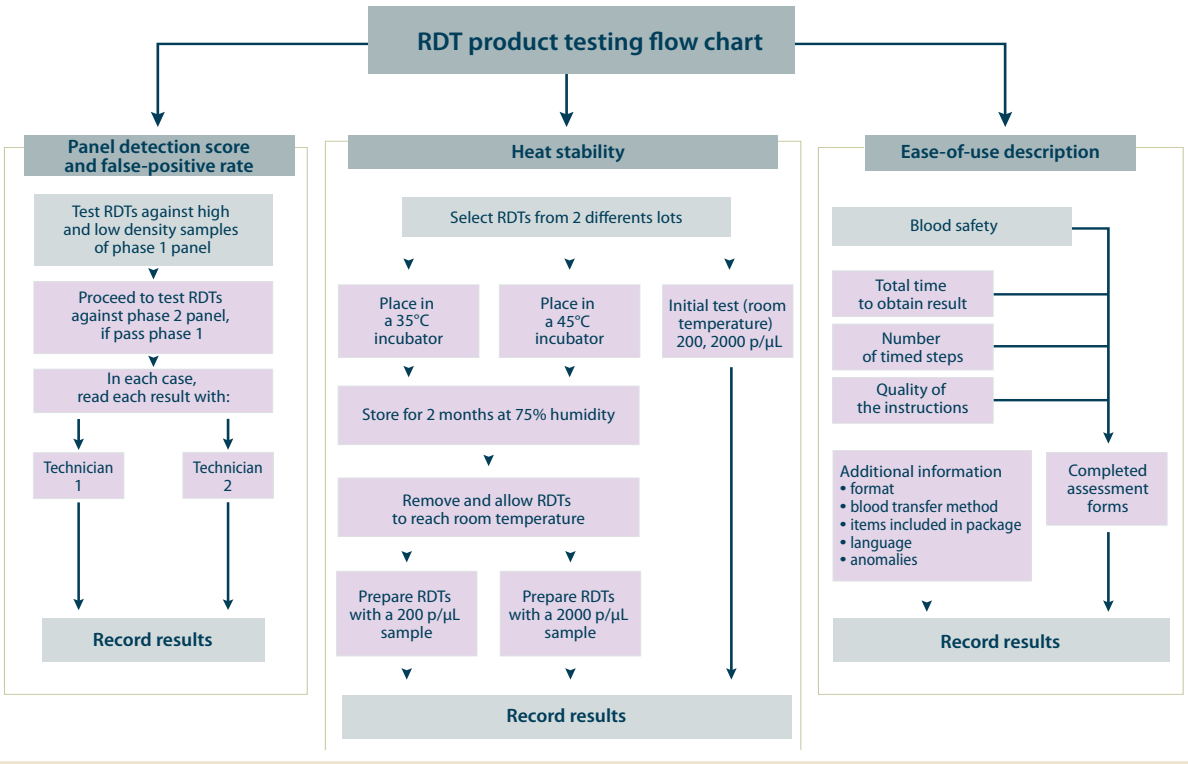
[1] PDS > 80% against high-density (2000 parasites/µL) *P. falciparum* in culture

Table 1b: Products due for compulsory resubmission in round 5

Manufacturer	Product name	Catalogue number	Participation in round 5[a]
Access Bio, Inc.	CareStart™ Malaria pLDH (PAN)	G0111	Yes
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131	Yes
	CareStart™ Malaria HRP2 (Pf)	G0141	Yes
Acon Laboratories, Inc	Malaria Plasmodium falciparum Rapid Test Device (Whole Blood)	IMA-402	No
Amgenix International, Inc.	OnSight - ParaQuick (Pan, Pf) Test	536-25DB	No
Biosynex	Immunoquick Malaria Falciparum	0502_K25	Yes
	Immunoquick Malaria +4	0506_K25	No
Diagnostics Automation/Cortez Diagnostics Inc.	Malaria P.F/Vivax	172110P-25	No
Human GmbH	Hexagon Malaria	58051	No
	Hexagon Malaria Combi	58024	No
IND Diagnostic Inc.	One Step Malaria Antigen Strip	820-1	No
Innovatek Medical Inc.	Quickstick Malaria Antigen Test[b]		No
Intec Products, Inc.	ADVANCED QUALITY TM MALARIA (p.f) POCT	ITP11002TC1	Yes
Inverness Medical Innovations, Inc.	Binax Now Malaria	IN660050	No
J. Mitra & Co. Pvt. Ltd	Advantage P.f. Malaria Card	IR016025	Yes
	Advantage Pan Malaria Card	IR013025	Yes
	Advantage Mal Card	IR221025	Yes
Premier Medical Corporation Ltd.	First Response® Malaria Ag HRP2	II3FRC	Yes
Span Diagnostics	Parahit-Total Device Rapid Test for *P. falciparum* and Pan malaria species	25989	No
Standard Diagnostics	SD Bioline Malaria Ag Pf	05FK50	Yes
Unimed International	FirstSign – Malaria Pf Card Test	-	No
	FirstSign – ParaView-2 (Pv + Pf) Card Test	2102CB-25	No

[a] The results of the first tests of the products in this list that were not retested in round 5 have been removed from tables S2 and S3 and figs S1 and S2.
[b] Co-listed with IND Diagnostics - One Step Malaria Antigen Strip (820-1)

Figure 3: Overview of malaria RDT product testing



5.3. Evaluation panels

RDTs were evaluated against three panels:

- *P. falciparum* culture lines (includes a subset, "manufacturer's panel") at low (200 parasites/µL) and high parasite density (2000 parasites/µL);
- wild-type *Plasmodium* species (*P. falciparum*, *P. vivax*) from naturally infected humans diluted with parasite-negative samples to low (200 parasites/µL) and high parasite density (2000 or 5000[1] parasites/µL). All samples are prepared from isolates that express HRP2; and
- a parasite-negative panel ("clean" samples and disease-specific or blood factor-specific samples).

An overview of sample collection and characterization is given in the methods manuals prepared for this purpose (*24*, *25*). Characterization results for each round are available on the WHO/GMP and FIND websites (*27*). Thus, each panel specimen was characterized for:

- species, by duplicate microscopy (two microscopists) and confirmation of mono-species infection by nested polymerase chain reaction (PCR);
- antigen concentration, by quantitative ELISA for HRP2, pLDH and aldolase; and
- the absence of malaria parasites by nested PCR and confirmatory testing for other diseases in the case of parasite-negative samples.

Most *P. falciparum* samples in the global specimen bank are also characterized according to HRP2 sequence by PCR amplification and sequencing. This is not performed on samples collected after 2009, as accumulated evidence indicates that HRP2 variation has no significant effect on RDT sensitivity (*28*). The geographical origin of all samples is recorded.

Panel composition

P. falciparum–cultured parasites panel

Twenty culture-adapted strains of *P. falciparum* from various geographical locations were selected, including 14 strains with type B HRP2 sequence, five with type A and one with type C. All specimens were derived from the CDC culture bank and diluted in O-positive blood from donors in the USA (*24*).

Wild-type parasite panel

The parasite-positive wild-type (clinical) panel consisted of samples from 100 cases of *P. falciparum* and 35 cases of *P. vivax malaria*, from 12 collection sites in Africa, Asia and

[1] Four (4%) of the 100 *P. falciparum* dilution sample sets contained 200 and 5000 parasites/µL, and two (6%) of the 35 *P. vivax* dilution sample sets contained 200 and 5000 parasites/µL.

South America (Fig. 2, 4a and 4b). Samples were collected from febrile patients and processed by standardized methods designed to preserve the target antigen concentration (*25*). After dilution and cryopreservation, the samples were transferred to the global bank (WHO specimen bank) at CDC for further characterization. Sample antigen (HRP2, pLDH, aldolase) concentrations determined by quantitative ELISA are given in Table 3. The results are based on 94 *P. falciparum* samples for pLDH, 99 *P. falciparum* samples for HRP2 and aldolase, 34 *P. vivax* samples for pLDH and 35 *P. vivax* samples for aldolase. This panel is highly comparable to those of previous rounds (Annex S1).

Negative blood sample panel

The negative panel consisted of 59 "clean" parasite-negative samples from donor-derived blood obtained in banks or from volunteers in non-endemic (USA) and endemic areas (Kenya, the Philippines and Senegal) that had been found to be malaria-negative by microscopy. The panel also contained 42 parasite-negative samples from donors with diseases that might be used in the differential diagnoses of malaria or that contained blood factors known to be common in the community or that could result in false-positive reactions in immunochromatographic tests (Table 2). All negative control samples were confirmed free of *Plasmodium* parasites by PCR amplification.

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

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

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

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

Figure 4a: Origin of phase 2 *P. falciparum* wild-type (clinical) samples (n=100)

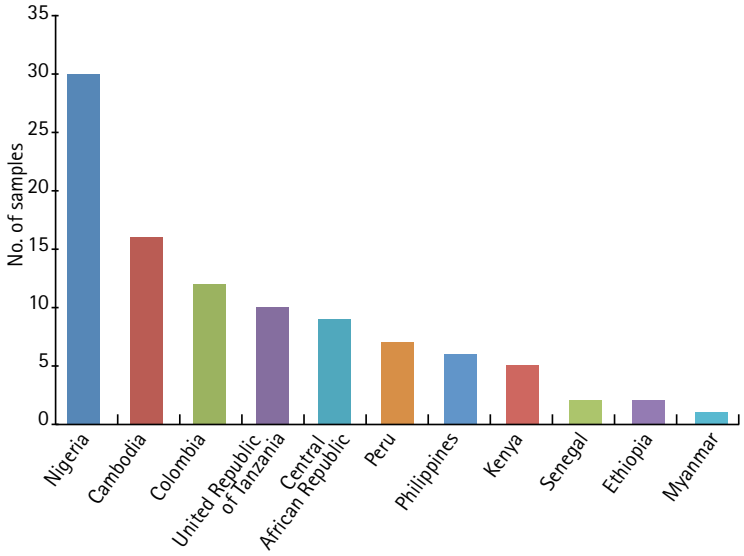


Figure 4b: Origin of phase 2 *P. vivax* wild-type (clinical) samples (n=35)

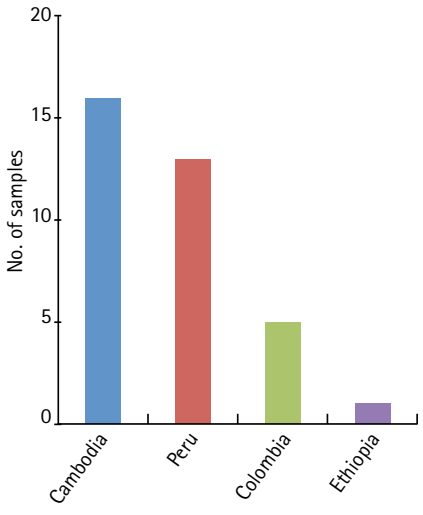


Table 3: Malaria antigen concentrations (ng/mL) in round 5 wild-type, low parasite density (200 parasites/µL) samples

	pLDH		HRP2	Aldolase	
	P. falciparum	*P. vivax*	*P. falciparum*	*P. falciparum*	*P. vivax*
Mean	15.5	16.8	11.7	1.5	8.1
Median	12.2	13.2	7.0	1.1	7.0
Maximum	43.0	47.9	62.5	7.7	15.0
Minimum	0.2	1.6	0.6	0.0	3.2
Standard deviation	11.4	12.6	13.2	1.5	3.3

5.4. RDT registration

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

5.5. Specimen panel registration

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

5.6. Test phases

The evaluation is divided into two phases. Each lot of RDTs is evaluated independently. Lots 1 and 2 of each product were tested alternately against defined sample sets,[1] testing of a set of lot 1 of all products was completed, then a set of lot 2 was tested, until both lots of all products had been tested against all panel samples.

Phase 1. A screening step is used to allow selection of RDTs that meet the 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 density. To progress to the full evaluation (phase 2), a product evaluated in phase 1 must achieve a minimum PDS of 80% against the samples containing 2000 parasites/µL.

Phase 2. Products from two lots are 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.

- Performance assessment: The mixed parasite-positive and parasite-negative panel comprised 100 *P. falciparum*, 35 *P. vivax* at two parasite densities (200 parasites/µL and 2000 (or 5000)[2] parasites/µL) and 100 parasite-negative controls.
- Heat stability evaluation: Testing of 15 RDTs from each of two lots against a single culture-derived *P. falciparum* isolate (Nigeria XII strain, *P. falciparum* HRP2 sequence type B with a typical antigen concentration) at 200 parasites/µL, five RDTs from each lot against *P. falciparum* Nigeria XII strain at 2000 parasites/µL, and four RDTs from each lot against a negative sample was performed after RDTs were maintained for 60 days at room temperature (< 25 °C), 35 °C and 45 °C, at 75% humidity.
- Ease-of-use assessment: After technicians had become familiar with the test device, they jointly described its blood safety characteristics, the quality of the instructions, the number of timed steps and the total time to a result, using a standard reference guide *(24)*.
- RDT anomalies: During testing, technicians regularly reported RDT anomalies according to the list below and guided by Fig. AS2.1. When anomalies were noted frequently, a digital photograph of at least one example was obtained.
  - red background
  - incomplete clearing (of blood in the results window)
  - failure to flow (blood and buffer did not run the length of the strip)
  - ghost test lines
  - patchy, broken test lines
  - diffuse lines
  - thin lines
  - strip misplaced in cassette
  - specimen pad not seen in sample window

5.7. Performing rapid tests

All RDTs were maintained at room temperature until first use. When applicable, the desiccant was inspected for colour changes, and products were discarded if they were present. RDTs were labelled with sample identification number, dilution and date test was performed. The tests were used according to the manufacturer's instructions, except that the recommended volume of blood was transferred by micro-pipette from the sample tube, and co-packaged blood transfer devices were not used. The result was recorded by a technician at the minimum specified reading time, and a second technician re-read the result within 30 min for internal monitoring and to obtain information for the manufacturer. Technicians were rotated and blinded to sample type and to each other's results during phase 2. Annexes 1 and 2 give a descriptive, illustrated summary of the test characteristics and steps and a guide to interpretation of results.

[1] A sample set consists of 13 *P. falciparum* specimens and five *P. vivax* specimens at 200 parasites/µL and 2000 parasites/µL and 13 malaria-negative samples.

[2] Four (4%) of the 100 *P. falciparum* dilution samples sets were at 200 and 5000 parasites/µL and two (6%) of the 35 *P. vivax* dilution sample sets were at 200 and 5000 parasites/µL.

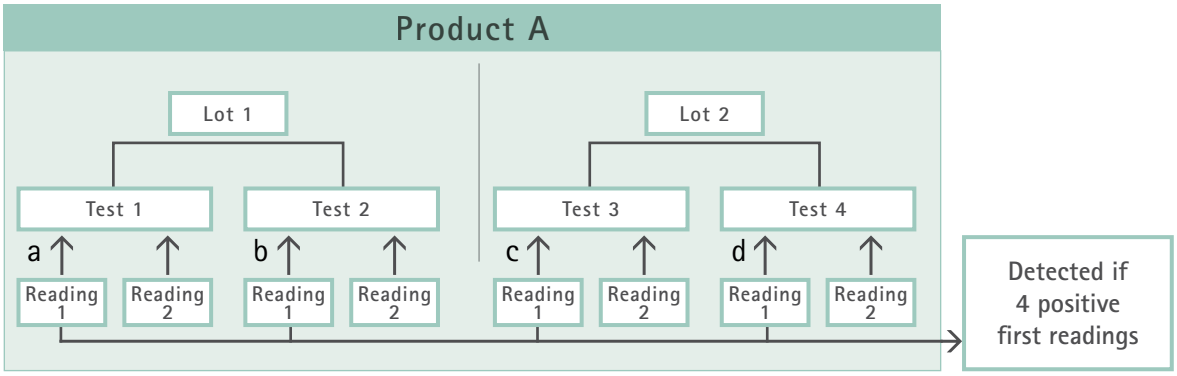
5.8. Interpreting the results

The 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 was recorded as "0" (no visible band) by either technician, the test was recorded as invalid.

Figs 5 and 6 illustrate the testing sequence at low and high parasite density.

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 30 min later[a]. A sample is considered detected only if all first test readings, from both lots, are positive, i.e. readings a, b, c and d must be positive.

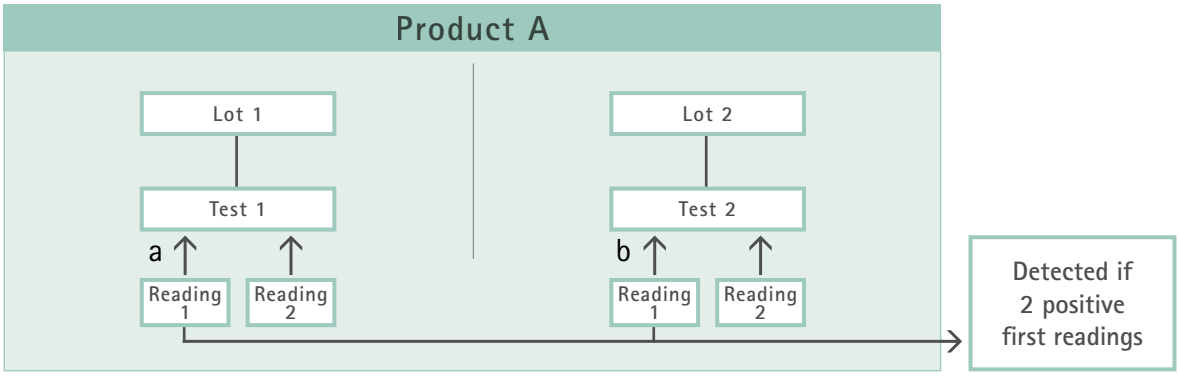


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[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 30 min later[a]. A sample is considered detected only if all first test readings, from both lots, are positive, i.e. readings a and b must be positive.



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

[a] Second reading results are for internal use only

6. DATA MANAGEMENT

Receipt of products was hand-recorded in a RDT register at the CDC as per standard operating procedures. Data associated with specimen collection and characterization were recorded first on hard-copy report forms as per the standard operating procedure at the collection sites (Fig. 2), the Hospital of Tropical Diseases (quantitative ELISA results) and the CDC (PCR results) and then entered directly into Excel followed by importation into a specially developed database.

The results of product panel testing and heat stability testing conducted at the CDC were recorded on report forms by each technician individually, as per the standard operating procedure. The results were entered in duplicate and analysed for discrepancies.

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

Individual product testing reports were sent to manufacturers on 14 March 2014 for a 30-day review period before publication of the final report. Raw data were made available to manufacturers upon request.

7. QUALITY ASSURANCE

Product testing follows standard operating procedures developed during previous testing, which are based on recommendations by expert consultants, with minor modifications by the Steering Committee before round 5 *(24)*. In particular, alternate testing of lots 1 and 2 on discrete sample sets, instead of sequential testing, was introduced, as was a standardized set of descriptions and terms for recording RDT anomalies. Overall, the quality of critical steps was controlled as described below.

7.1. Quality of malaria RDTs and their use

All RDTs were stored in a controlled environment at room temperature (≤ 25 °C). The pouch was opened, and, if applicable, the desiccant was checked for colour change immediately before use. The manufacturer's instructions were followed, except for use of the blood transfer device provided by the manufacturer: a micropipette was used to ensure the correct blood volume.

A temperature monitoring device was offered to manufacturers to be shipped with the RDTs to the testing site (CDC). Logs were analysed for temperatures above or below the manufacturer's recommended storage conditions.

7.2. Quality and objectivity of the RDT reading results

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

All wild-type parasite samples used in phase 2 were randomized with parasite-negative samples and re-labelled for blinded reading of the RDT results.

7.3. Quality of WHO specimen bank samples

Standard operating procedures were established for the preparation of all specimen bank samples *(25)*. Culture lines of parasites and wild-type samples were selected on the basis of previous evidence and data from specific studies. All diluted parasite samples were stored and transported at –70 °C and were used only once within 8 h of thawing.

7.4. Quality of the product testing site

The Division of Parasitic Diseases and Malaria, Center for Global Health, CDC, is the main operating component of the Department of Health and Human Services of the USA, which deals with malaria control and prevention. Laboratories within the Division are accredited by Clinical Laboratory Improvement Amendments and are monitored by an internal quality management system.

8. ETHICAL CONSIDERATIONS

Each specimen collection site obtained approval from a WHO research ethics review committee and/or a local institutional review board for specimen collection, transport and archiving of blood samples for the purpose of product testing, lot testing and quality assurance.

9. DATA ANALYSIS

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

As shown in Figure 5, a product must return four positive test results at the manufacturers' recommended minimum reading time (two from lot 1, two from lot 2 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 (Fig. 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 of the test to detect antigen. The PDS for *P. falciparum* indicates an RDT result that confirms the presence of *P. falciparum* when tested against cultured and wild-type *P. falciparum* samples, while the *P. vivax* PDS indicates *Plasmodium*-positive/*P. falciparum*-negative results when tested with wild-type *P. vivax* samples.

The positivity rate is the percentage of all tests of a particular product that returned a positive 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 groups: those with incorrect species identification and those that returned a positive result for samples that do not contain *Plasmodium* spp. Specifically, the false-positive rate is the percentage of all tests of a particular product that returned a positive test result when it should not have, in results obtained at the manufacturer's recommended minimum reading time.

9.2.1 Incorrect species identification

A test is considered to have returned an incorrect species result if a positive *P. falciparum* test line appears when testing a sample containing non-*P. falciparum (P. vivax)* parasites. Fig. 7 illustrates the various possibilities for incorrect species identification in combination tests. For example, if *P. falciparum* samples result in only a visible pan-specific (or non-*P. falciparum*-specific) test line in combination

Figure 7: Classification of incorrect species identification with combination malaria RDTs

Pf/pan combination tests

Panel sample	Pf + / Pan –	Pf + / Pan +	Pf – / Pan +	Pf – / Pan –
Pf	✚	✚	False-positive (non-Pf)	Negative
Pv	False-positive (Pf)	False-positive (Pf)	✚	Negative

Pf/Pv combination tests

Panel	Pf + / Pv –	Pf + / Pv +	Pf – / Pv +	Pf – / Pv –
Pf	✚	✚	False-positive (non-Pf)	Negative
Pv	False-positive (Pf)	False-positive (Pf)	✚	Negative

tests, the result is considered to be a false-positive for non-*P. falciparum* parasites.

9.2.2 False-positive results for *Plasmodium*-negative samples

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

9.3. Band intensity

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

9.4. Lot agreement

Agreement between test lots is calculated from the number of samples that return 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. High inter-lot agreement indicates consistency in detecting malaria parasites. When one test is invalid and the other positive, positive agreement is recorded. Fig. 8 shows sample calculations for lot agreement.

9.5. Invalid tests

Invalid tests are those deemed invalid during testing of both lots, with samples at 200 parasites/µL and 2000 (or 5000) parasites/µL.

9.6. Heat (thermal) stability

The results of heat stability testing are reported as the number of positive tests against one cultured *P. falciparum* parasite sample at 200 and 2000 parasites/µL based on the first reading of two lots at each parasite density (maximum score, 30 against 200 parasites/µL samples and 10 against 2000 parasites/µL samples)[2] and mean band intensity (for positive tests only based on the first reading) after the lots were stored at room temperature (< 25 °C) and at 35 °C and 45 °C for 2 months.

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

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

Figure 8: Explanation of lot agreement calculation

	Test results (1= positive, 0 = negative)				Derived values (1= both positive, 0 = both negative)			
	Lot 1		Lot 2		(a)	(b)	(d)	(f)
	Test 1 reader 1	Test 2 reader 1	Test 1 reader 1	Test 2 reader 1	Lot 1 tests	Lot 2 tests	Comparison of lot results	Contribution to overall
Sample 1	1	1	1	1	1	1	1	1
Sample 2	1	0	0	0	Disagree	0	Can't compare	0
Sample 3	0	1	0	1	Disagree	Disagree	Can't compare	0
Sample 4	0	0	0	0	0	0	0	0
Sample 5	1	1	1	1	1	1	1	1

PDS = sum (f) / number of samples = 2/5 = 40
Lot 1 PDS = sum (a) / number of samples = 2 / 5 = 40
Lot 2 PDS = sum (b) / number of samples = 2 / 5 = 40
Positivity = number of positive results / total number of tests = 11 / 20 = 55%

Agreement between tests = (count number of 0 and 1s in (a) and (b)) / (number of samples x 2 lots) = 7 / 10 = 70%
Agreement between lots = (count number of 0 and 1s in (d)) / (number of samples -- number of "can't compare" in (d)) = 3 /3 = 100%

Note: reader 1 = Technician 1 in raw data files

10. RELATION BETWEEN PARASITE DENSITY AND ANTIGEN CONCENTRATION

Malaria RDTs detect parasite-derived antigen. The relation of the concentration of antigen available from the blood sample (after lysis of red cells and parasites) to the peripheral parasite density varies widely because of a series of host and parasite factors (Box 4).

In establishing panels for the product testing programme that reflect possible variation in antigen concentration for parasitaemia of 200 parasites/µL, a large number (> 300) of wild-type parasite samples from clinical cases in different geographical areas were analysed by quantitative ELISA for HRP2, pLDH and aldolase. Only samples with antigen values within the 90th percentile for HRP, pLDH and aldolase were selected for the performance panels. Furthermore, the distribution of antigen levels for HRP2, pLDH and aldolase was compared with that in previous rounds to ensure consistency. No statistically significant differences in median antigen levels between the panels for rounds 1–5 were detected for any of the three antigens ($p > 0.1$, Kruskal-Wallis test). Therefore, the panels used for the product testing rounds can be considered comparable (Annex S1).

Box 4. Explanations for variable antigen concentrations in samples with the same parasite density

- variation in antigen expression among isolates
- different durations of infections (accumulating antigens)
- different parasite growth stages at the time of collection (expressing different levels of antigens)
- presence of circulating HRP2 from previous cycles of growth
- HRP2 produced by parasites sequestered in the host's vascular tissues that cannot be accounted for in the estimate of parasite density on the blood slide (29)

11. LABORATORY VERSUS FIELD-BASED MALARIA RDT EVALUATIONS

Despite the strengths of the product testing programme, the evaluations are not completely analogous to field testing of malaria RDTs. In order to compose a panel that could be used to evaluate RDTs reproducibly, blood samples must be diluted, frozen and stored below –70 °C; however, blood that has undergone freezing and thawing is lysed and may not have exactly the same characteristics as fresh blood. Another difference from field evaluation is use of a micro-pipette to place blood in the RDT device rather than the blood transfer device provided by the manufacturer. This is necessary because blood is collected from a cryo-tube rather than a finger-prick, and the blood transfer devices provided with the different products vary (*30*). This technique also ensures the consistency of testing by reducing the likelihood of operator error. As all samples in the panel used for the evaluation are prepared from parasites that express HRP2, the results will not be predictive of field trial results of parasite populations with significant levels of HRP2 deletion (*10*, *11*).

In addition, the population frequency of blood immunological factors or infectious diseases, which can result in false-positive results, may vary. Therefore, the sensitivity and specificity of an RDT in the field depends on the epidemiological situation. The evaluation reported here does not predict sensitivity or specificity in a given field situation but the rates of detection of target antigens and false-positive results of RDTs against a standardized panel in a controlled, repeatable manner. As the panel is meant to be a close approximation of field samples, the detection rates of different products will be reflected in similar differences in the field. The panel is designed to include a large number of samples that are close to the limit of detection of RDTs (200 parasites/µL) and is therefore likely to discriminate between them more clearly than a field trial. It follows that in settings where parasite density is very high, no differences in the PDS and positivity rates of tests or much smaller differences will be observed compared to those reported against the WHO evaluation panel. Furthermore, where the parasite density is very low, the detection rates may be lower than those reported here.

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 in a programme (e.g. ease-of-use characteristics). Such trials should have carefully defined objectives and procedures designed to achieve them. Trials to determine the probable field sensitivity and specificity of a product also have a place but require large samples and populations with low parasite densities if significant differences are to be found between well-performing products; they must also be closely controlled and are therefore expensive. Such trials do not allow comparison of a large number of products. WHO has published recommendations for good practice in malaria field trials (*31*), which should be followed to improve the reproducibility and quality of the results.

12. RESULTS

12.1. Summary

Round 5 of WHO malaria RDT product testing provided results for 42 products evaluated against *P. falciparum* culture samples, and all the products proceeded to evaluation against wild-type samples collected from parasitaemic patients on three continents and a large panel of parasite-negative samples. Heat stability was assessed at the temperatures commonly encountered in malaria-endemic countries. Thirteen research institutes were engaged in either sample collection or sample characterization to establish the evaluation panels. Between January 2013 and December 2013, approximately 58 400 RDTs were tested at the CDC.

The main results are presented in Tables 4 and 5, which group the RDTs by the species they are designed to detect, i.e. *P. falciparum* only, *P. falciparum* and non-*falciparum* species, *P. falciparum* and *P. vivax*, *P. vivax*, *ovale* and *malariae*, pan *only* or all malaria species without discrimination. Note that only tests against *P. falciparum* and *P. vivax* samples were evaluated, and the evaluation does not therefore indicate whether a product intended to detect other species can do so.

PDS 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 according to WHO-recommended RDT procurement selection criteria (Box 3). When choosing an appropriate product, it is important also to review its thermal stability (Table 6) in the context of the expected conditions of transport and storage in the field.

The results of the evaluation are listed below.

- The overall range of results against wild-type and negative samples, including PDS, positivity rate, false-positive rate and heat stability, were similar to those reported in rounds 1–4 (*3*–*6*). The median PDS for *P. falciparum* was slightly lower at low parasite densities than in the previous round (89.3% vs 85%), and no products scored a PDS of 100% in round 5. The PDS for *P. vivax* at low densities has improved consistently since round 1 (median, 30%), the results for rounds 2, 3, 4 and 5 being 75.0%, 51.4%, 61.8% and 65.7% respectively. The median false-positive rate remained consistently at about 1%; however, the range of false-positive rates increased significantly with each round of testing (upper limit in rounds 1–5: 28%, 37%, 44%, 99.1% and 81.3%). Some products with high false-positive rates also had high PDS, underscoring the importance of reviewing all aspects of product performance.
- A number of RDTs consistently detected malaria at a low parasite density (200 parasites/µL), had low false-positive rates, were stable at tropical temperatures, are relatively easy to use and can detect *P. falciparum*, *P. vivax* or both infections, increasing the number of available well-performing tests from that in rounds 1–4.
- The performance of products varied widely at low parasite density (200 parasites/µL), but most showed a high detection rate for *P. falciparum* and *P. vivax* at 2000 (or 5000) parasites/µL.
- *P. falciparum* tests targeting the HRP2 antigen had the highest PDS for *P. falciparum,* and the two products with the poorest performance at 200 parasites/µL targeted *P. falciparum*-specific pLDH antigen. Two resubmitted pan-only tests maintained good PDS for *P. falciparum* at low parasite density.
- Several combination tests achieved PDS at the upper end of the range for both *P. falciparum* and *P. vivax*. (Fig. S3).
- The test performance of some products varied between lots.
- Most combination tests in which HRP2 is used for detection of Pf return positive results predominantly only on the HRP2 band at lower densities of Pf. This reinforces manufacturers instructions to classify Pf infections as either HRP2 test line-positive alone or in combination with the pan-pLDH line.

Tables 4 and 5 summarize the performance of malaria RDTs against cultured *P. falciparum* parasites, blood containing wild-type *P. falciparum* and *P. vivax* parasites and *Plasmodium* spp.-negative samples. Detailed phase-1 and phase-2 results of product testing are given in annexes 3 and 4, respectively. The data are shown graphically in Figs 9–27.

Table 4: Summary phase-1 performance of 42 malaria RDTs against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite density (parasites/µL)

Product	Catalogue number	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=160)
			200 parasites/µL	2000 parasites/µL	200 parasites/µL (n=80)	2000 parasites/µL (n=40)	
Pf only							
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	95.0	100.0	NA	NA	0.0
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	85.0	100.0	NA	NA	0.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	100.0	100.0	NA	NA	0.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	100.0	100.0	NA	NA	0.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	100.0	100.0	NA	NA	0.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	95.0	100.0	NA	NA	0.6
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	95.0	100.0 (19)	NA	NA	1.3
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	100.0	100.0	NA	NA	0.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	100.0	100.0	NA	NA	0.0
Pf and pan							
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	85.0	100.0	0.0 (78)	0.0	2.5
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	95.0	100.0	0.0	0.0 (39)	0.6
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	100.0	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	90.0	100.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	95.0	100.0	0.0	0.0	0.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	100.0	100.0	0.0	0.0	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	100.0	100.0	0.0	0.0	0.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	95.0	100.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	95.0	100.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	90.0	100.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	90.0	100.0	0.0	0.0	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	85.0	100.0	0.0	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	95.0	95.0	1.3	2.5	0.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	60.0	100.0	0.0	0.0	0.0
Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	0.0 (77)	0.0	2.5
Malaria pf-LDH/PAN-LDH Antigen Test Device	MFV-124	AZOG, INC.	5.0	100.0	3.8	0.0	0.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	100.0	100.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	100.0	100.0	0.0 (79)	0.0	0.6
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	100.0	100.0	0.0	0.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	100.0	100.0	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	95.0	100.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	100.0	100.0	0.0	0.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	90.0	100.0	0.0	0.0	0.6
Pf and Pv/Pvom							
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	100.0	11.3	97.5	0.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	90.0	95.0	1.3 (78)	0.0	1.3
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	95.0	100.0	13.8	95.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	95.0	100.0	53.8	35.0	0.0

Table 4 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=160)
			200 parasites/µL	2000 parasites/µL	200 parasites/µL (n=80)	2000 parasites/µL (n=40)	
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	95.0	100.0	1.3	0.0	0.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	95.0	100.0	2.5	2.5	0.0
Pan only							
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	65.0	100.0	NA	NA	0.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	95.0	100.0	NA	NA	0.0

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

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

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

Table 5: Summary phase-2 performance of 42 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=1214)
			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=100)	Pv samples (n=35)	Pf samples (n=100)	Pv samples (n=35)	False-positive non-Pf infection[c] (n=400)	False-positive Pf infection[d] (n=140)	False-positive non-Pf infection[c] (n=200)	False-positive Pf infection[d] (n=70)	False-positive *Plasmodium* spp. infection (n=236)	
Pf only												
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	53.0	NA	93.0	NA	NA	3.6	NA	5.7	7.7 (233)	0.4
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	88.0	NA	100.0	NA	NA	2.1	NA	1.4	0.9 (235)	0.3
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	95.0	NA	100.0	NA	NA	0.7	NA	0.0	0.4	0.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	72.0	NA	93.0	NA	NA	3.6	NA	4.3	5.1 (234)	0.2
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	79.0	NA	91.8 (98)	NA	NA	11.4	NA	12.9	10.6 (235)	0.7
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	95.0	NA	99.0	NA	NA	0.0	NA	2.9	0.0	0.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	84.0	NA	100.0	NA	NA	2.1	NA	1.4	5.1 (235)	0.1
Pf and pan												
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	66.0	37.1	92.0	97.1	0.3	0 (139)	0.0 (199)	0.0	7.3 (234)	0.4
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	100.0	97.1	0.3 (389)	6.7 (134)	0.0 (197)	1.4	8.7 (231)	2.1
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	94.0	97.1	1.5	0.7	0.5	0.0	0.4	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	100.0	100.0	3.5	0.0	0.0	0.0 (69)	0.0	0.2
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	77.0	77.1	99.0	97.1	0.8	0.7	0.5 (198)	0.0	4.7	0.2
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	77.0	77.1	94.0	100.0	0.5	0.7	2.0	0.0	0.4	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	90.0	94.3	100.0	100.0	1.5	0.7	0.0	0.0	0.4	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	89.0	60.0	99.0	85.7	0.3	12.1	0.5	7.1	12.7	0.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	100.0	97.1	0.3	2.9	0.0	1.5 (67)	2.1	0.2
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	83.0	80.0	100.0	100.0	0.3	0.7 (139)	0.0	0.0	1.3 (235)	0.3
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	85.0	74.3	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	100.0	97.1	0.0	0.0	0.0	0.0	0.0 (235)	0.2
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	96.0	88.6	0.0	13.6	0.0	7.1	10.6	0.1
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	90.0	91.4	100.0	97.1	0.5 (396)	0.0 (138)	0.0 (199)	1.4	0.9 (235)	0.7
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	93.0	40.0	98.0	94.3	0.3	4.3	0.5	2.9	3.0	0.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	95.0	97.1	0.0 (398)	4.3	0.0 (199)	0.0	0.9	0.2
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	100.0	100.0	0.0 (398)	0.7 (138)	0.0 (199)	0.0 (69)	0.4 (232)	1.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	41.0	8.6	97.0	45.7	22.5	47.9	1.5	35.7	81.3 (235)	0.1
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	95.0	28.6	100.0	40.0	0.0	38.6	0.0	40.0	39.4	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	100.0	94.3	0.5 (399)	9.3	0.0	4.3	15.3	0.1
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	86.0	88.6	100.0	97.1	0.0 (399)	0.0	0.0	1.4	1.3	0.1
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	92.0	37.1	100.0	97.1	0.5	0.7	0.0 (199)	1.4	4.2	0.1
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	74.0	40.0	94.0	88.6	2.0	2.9	0.5	5.7	14.0	0.0

Table 5 *(continued)*

Product	Catalogue number	Manufacturer	Panel detection score[b]				False-positive rates (%)				Total false-positive rates[e] (%)	Invalid rate (%) (n=1214)
			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=100)	Pv samples (n=35)	Pf samples (n=100)	Pv samples (n=35)	False-positive non-Pf infection[c] (n=400)	False-positive Pf infection[d] (n=140)	False-positive non-Pf infection[c] (n=200)	False-positive Pf infection[d] (n=70)	False-positive *Plasmodium* spp. infection (n=236)	
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	94.0	91.4	99.0	97.1	0.8	0.7	0.5	1.4	0.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	97.0	94.3	0.0	0.7 (139)	0.5 (199)	0.0 (69)	1.3 (235)	0.3
Pf and Pv/Pvom												
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	81.0	34.3	99.0	100.0	16.5	0.0	85.5	0.0	0.4 (235)	0.2
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	97.0	94.3	1.5 (391)	6.5 (138)	3.6 (195)	2.9	0.9 (232)	2.5
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	100.0	100.0	27.3 (399)	5.8 (139)	87.4 (199)	4.3 (69)	3.0 (232)	0.7
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	100.0	100.0	21.5	53.6	9.0	34.3	77.1	0.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	63.0	37.1	91.0	85.7	2.0 (399)	5.7	0.5	2.9	6.4	0.1
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	87.0	28.6	98.0	97.1	1.5 (399)	2.9	1.5	2.9	2.1	0.1
Pan only												
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	98.0	100.0	NA	NA	NA	NA	0.4	0.0
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] 4 (4%) of the 100 *P. falciparum* dilution sample sets had 200 and 5000 parasites/µL and 2 (6%) of the 35 *P. vivax* dilution sample sets had 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

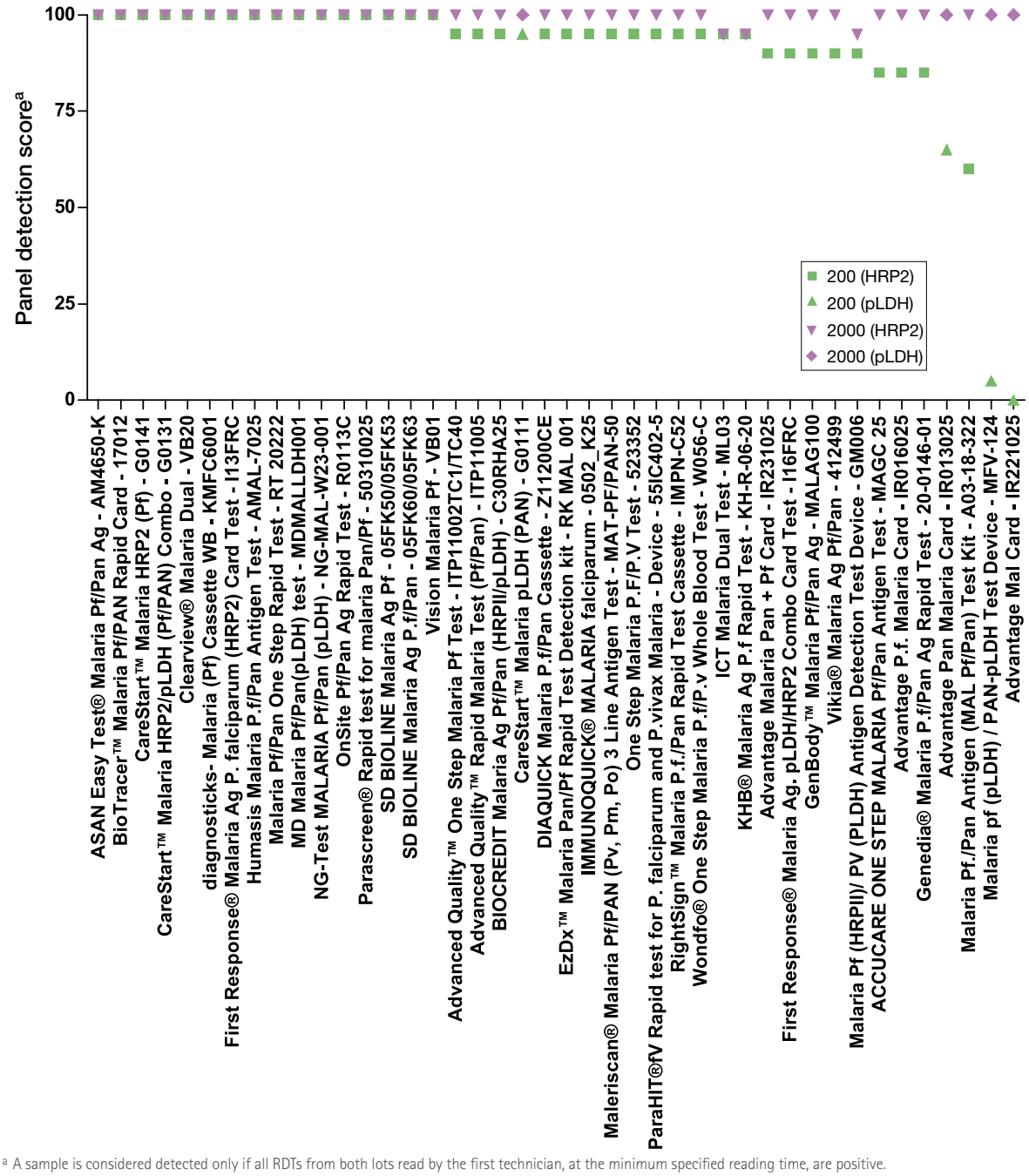
[e] The total number of times a positive result for malaria was generated when it should not have been

Performance measure	Recommended WHO procurement criteria
Panel detection score for Pf and Pv 200/µL samples	≥ 75%
False-positive rates against clean-negatives	< 10%
Invalid rate	< 5% of tests conducted

12.2. Phase 1: *P. falciparum* culture panel

All the tests consistently detected ≥ 95% of cultured *P. falciparum* parasites at high parasite density (2000 or 5000 parasites/µL); however, the PDS was highly variable (0–100%) at low parasite density (200 parasites/µL). At low parasite density, the products with the highest PDS targeted HRP2 (Fig. 9).

Figure 9: Phase-1 *P. falciparum* panel detection score of malaria RDTs at low (200) and high (2000) parasite density (parasites/µL) according to target antigen type (HRP2 or pLDH)



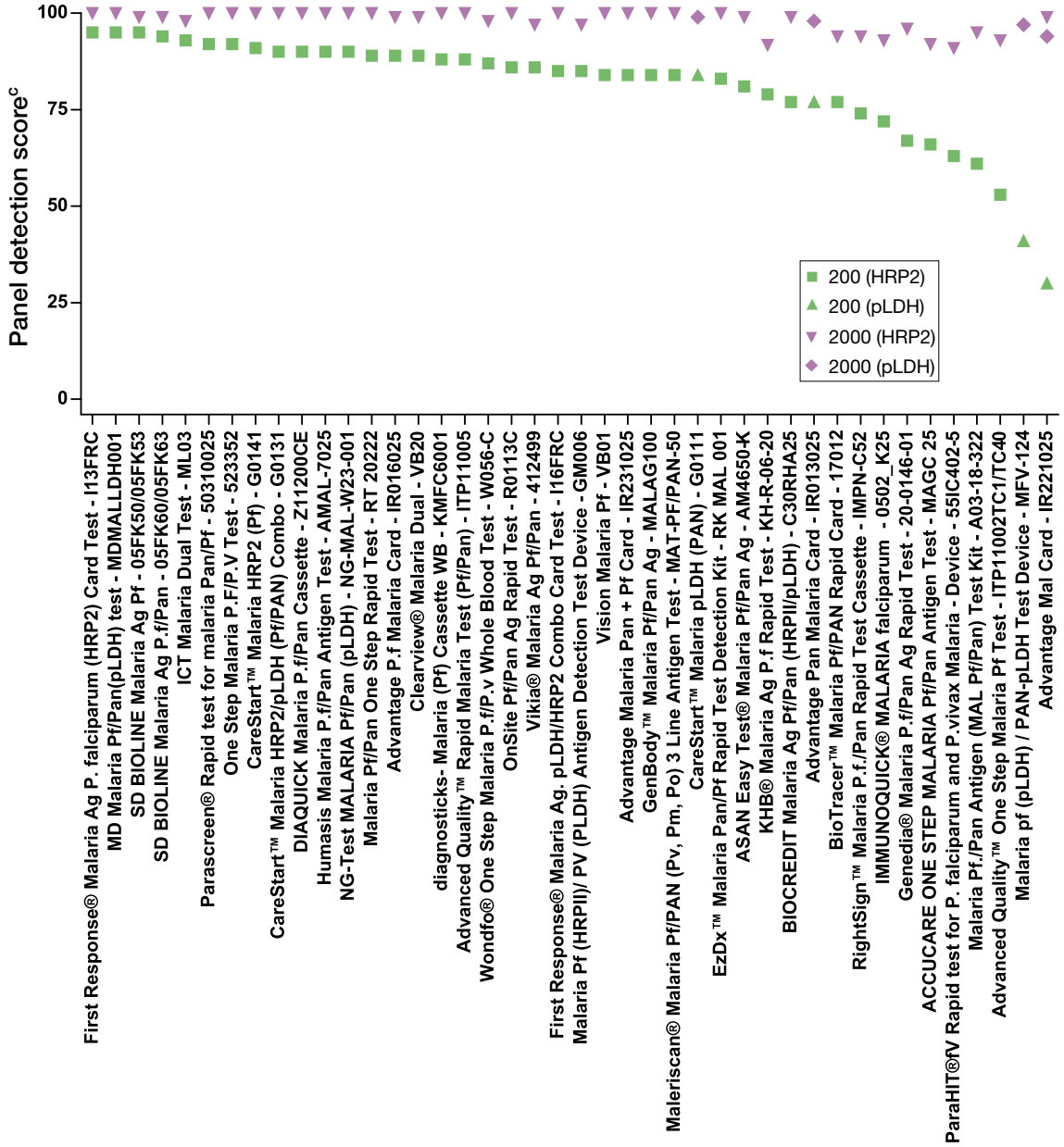
[a] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

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

12.3.1 *P. falciparum* detection

All 42 products in round 5 were designed to detect *P. falciparum*. As in phase 1, most of the tests (34; 81%) had a PDS ≥ 95% of *P. falciparum* samples at high parasite densities. Seven of the nine products specific for *P. falciparum* alone achieved a PDS ≥ 75% against samples with low parasite density (Fig. 10).

Figure 10: 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] 4 (4%) of the 100 *P. falciparum* dilution samples sets had 200 and 5000 parasites/µL and 2 (6%) of the 35 *P. vivax* dilution sample sets had 200 and 5000 parasites/µL.

[b] Phase-2 evaluation panel consisted of 100 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 the minimum specified reading time, are positive.

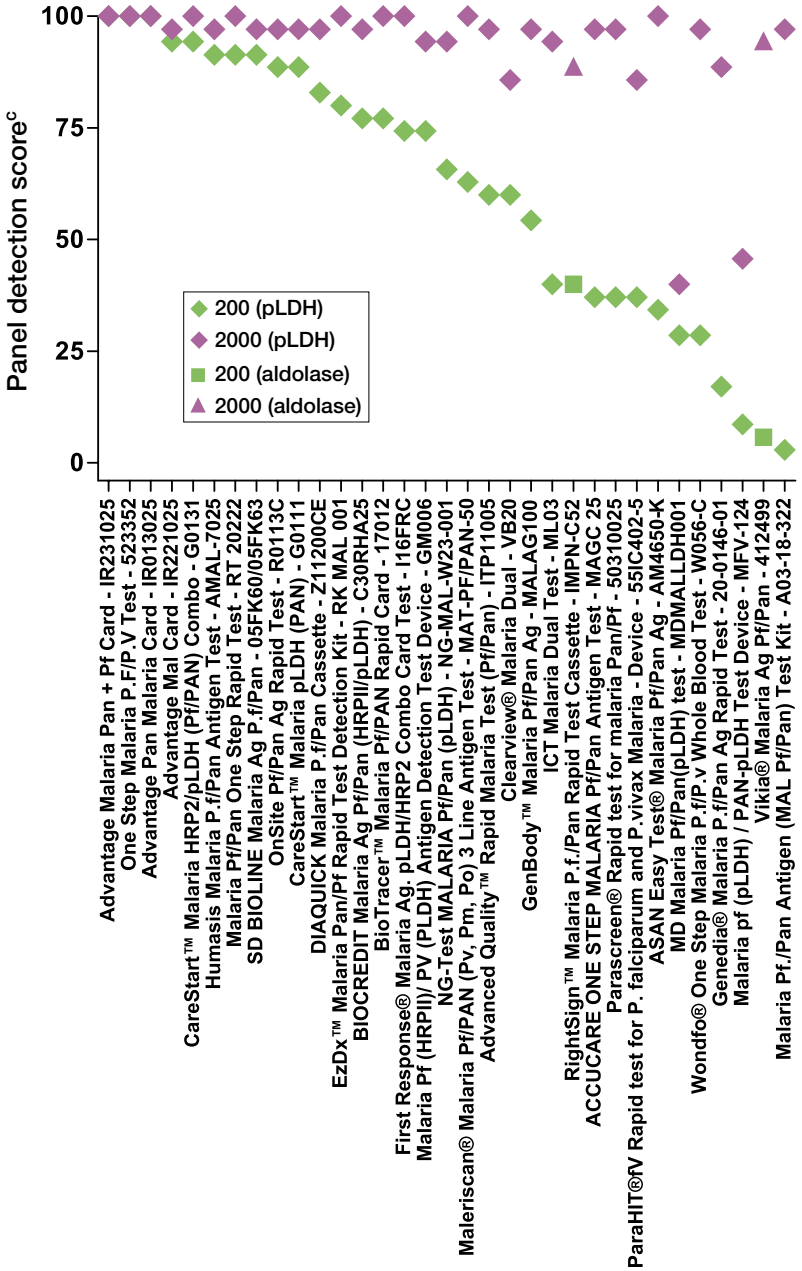
12.3.2 *P. vivax* detection

Fig. 11 shows that 31 of 33 (94%) products designed to detect *P. vivax* consistently detected ≥ 75% at high parasite density (2000 or 5000 parasites/µL), and 14 (42%) achieved the same threshold of PDS against samples with 200 parasite/µL. The overall detection rate in low parasite density wild-type *P. vivax* samples was lower than that for *P. falciparum*. At a low parasite density (200 parasite/µL), only 8 products had a PDS ≥ 90%, and 19 had a PDS < 75% (Table 5).

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

Of the 33 pan-specific and combination tests, 13 (39%) had a PDS ≥ 75% for both *P. falciparum* and *P. vivax* at a low parasite density (200 parasites/µL) (Table 5). These included the two pan-specific only tests. Several performed well at a high parasite density.

Figure 11: Phase-2 *P. vivax* panel detection score of malaria RDTs at low (200) and high (2000[a]) parasite density (parasites/µL) according to target antigen type (aldolase, pLDH)[b]



[a] 2 (6%) of the 35 *P. vivax* dilution sample sets had 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 the minimum specified reading time, are positive.

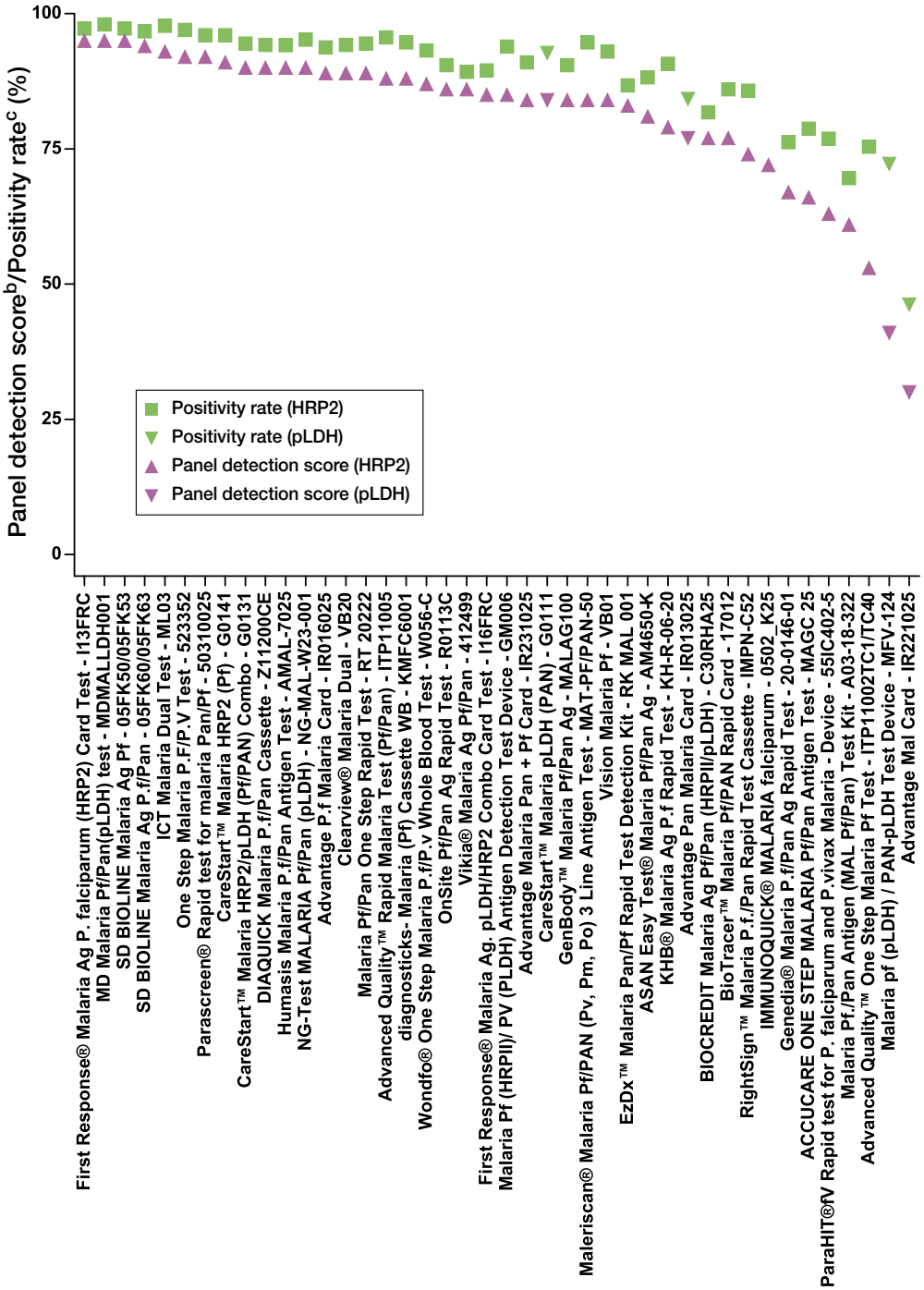
12.3.4 *P. falciparum* and *P. vivax* positivity rate

The positivity rate was measured in addition to the PDS, to measure the number of times a test returned a positive result. As expected, the positivity rates were higher than the PDS but mirrored the PDS against wild-type *P. falciparum* and *P. vivax* samples (Figs 12 and 13).

12.3.5 Band intensity

Although RDTs do not provide quantitative results, the technicians graded positive results according to a standard colour chart and calculated the mean band intensity for positive results (Annex 4, tables A4.2 and A4.3). A positive correlation was found between the PDS and band intensity (Spearman rank correlation, $r = 0.67$, $p < 0.001$ for the *P. falciparum* panel and $r = 0.66$, $p < 0.001$ for the *P. vivax* panel).

Figure 12: Phase-2 *P. falciparum* panel detection score and positivity rate at 200 parasites/µL[a]



[a] Phase-2 evaluation panel consisted of 100 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.

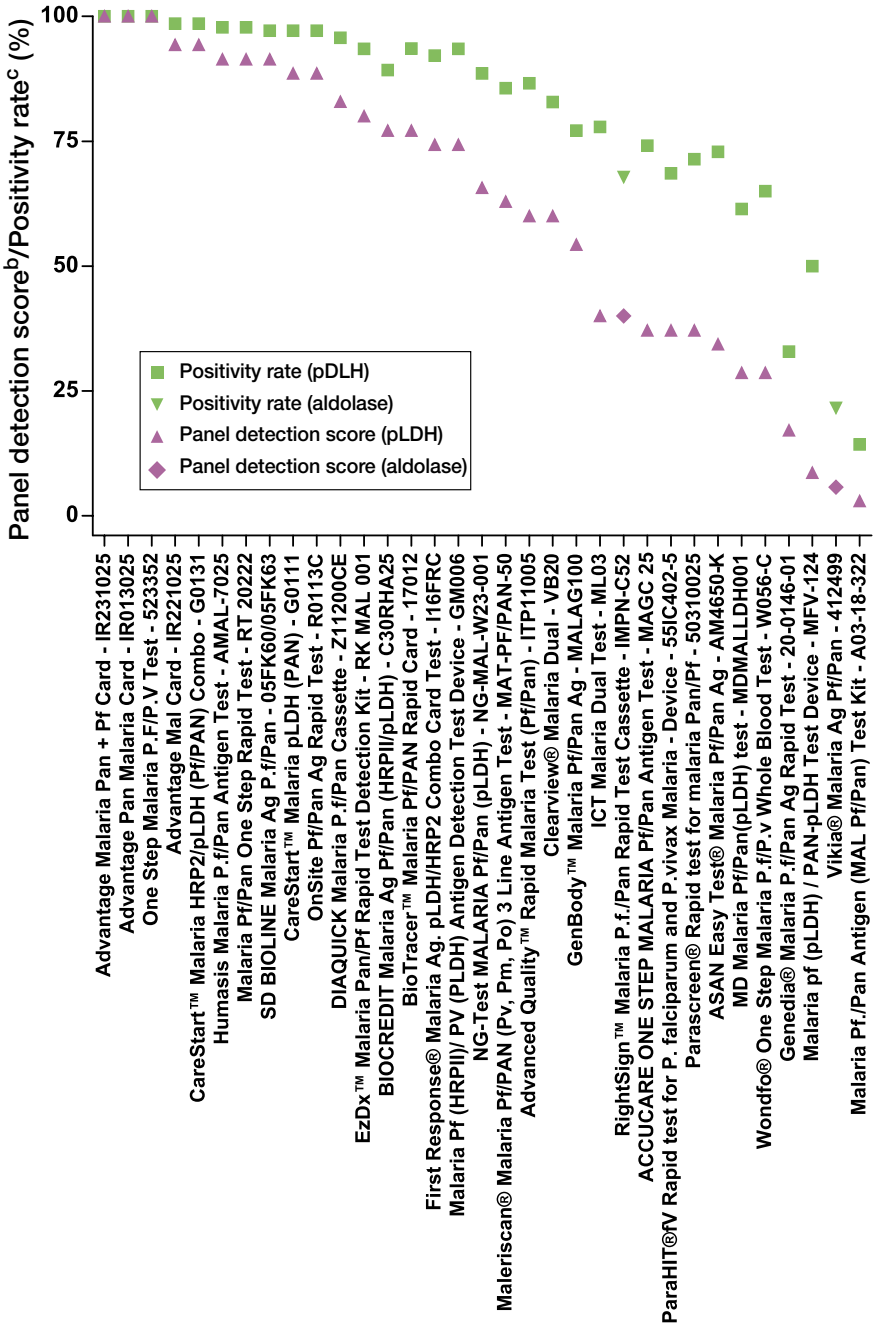
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

[c] The total number of times a test returned a positive result divided by the total number of times it should have (x 100).

Of the combination RDT products containing a pan test band that gave a positive indication for *P. falciparum* against low-density *P. falciparum* samples, 44.1% (3850/8721) gave positive results on both the *P. falciparum* and pan test bands, and 55.9% (4871/8821) were positive only on the *P. falciparum* test band. Of HRP2-detecting products, 41.9% (3454/8247) of those that detected *P. falciparum* showed both the *P. falciparum* (HRP2) and the pan test band (pan-pLDH) as positive, while 58.1% (4793/8247) were positive only on the *P. falciparum* HRP2 test band. The values were 83.5% (396/474) and 16.5% (78/474) for the non-HRP2-based products.

When the pan test band in the combination products was positive, the mean intensity of the band was 1.07 (standard deviation, 0.23), which was significantly lower than the corresponding mean *P. falciparum* test band intensity (mean, 2.04; standard deviation, 0.42), when tested against the lower-density *P. falciparum* parasite panel (paired *t* test, $p < 0.001$). There was no correlation between the mean intensity of the pan test band and the *P. falciparum* test band ($r = -0.049$, $p = 0.805$).

Figure 13: 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 the minimum specified reading time, are positive.

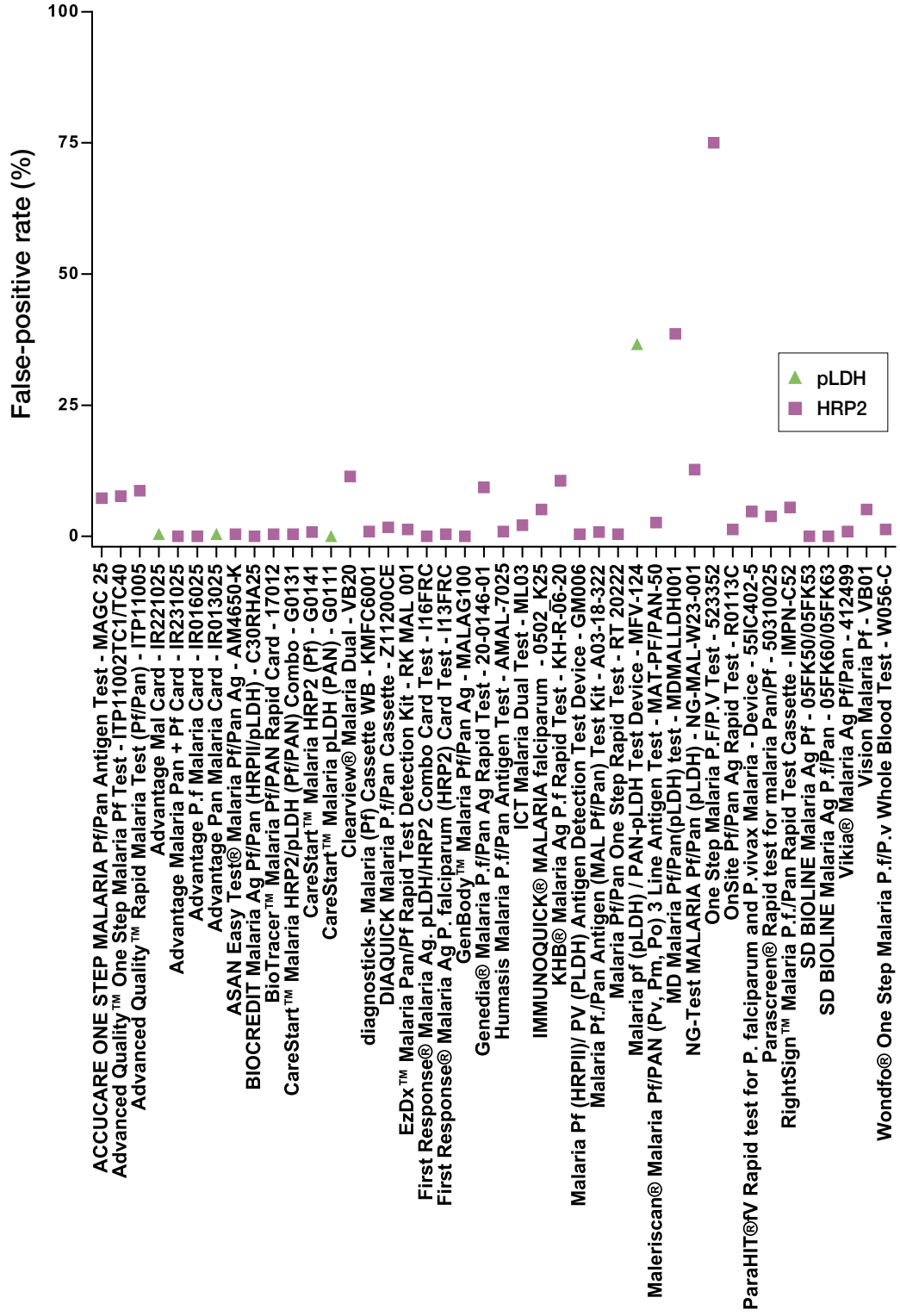
[c] The total number of times a test returned a positive result divided by the total number of times it should have (x 100).

12.3.6 False-positive rates

Eight (19%) tests had false-positive rates > 10% on 59 clean-negative samples on any test line (Figs 14 and 15). The same eight tests also had high false-positive rates for samples containing other pathogens and immunological abnormalities.

Only one test with a low false-positive rate (< 10%) on clean-negative samples returned high false-positive rates (range, 8.3–100%) against samples from patients with other blood pathogens. Several tests with low false-positive rates (< 10%) on clean-negative samples had high false-positive rates against samples with immunological blood abnormalities,

Figure 14: Phase-2 *P. falciparum* (*P. falciparum* test line) false-positive rate against clean-negative samples[a]

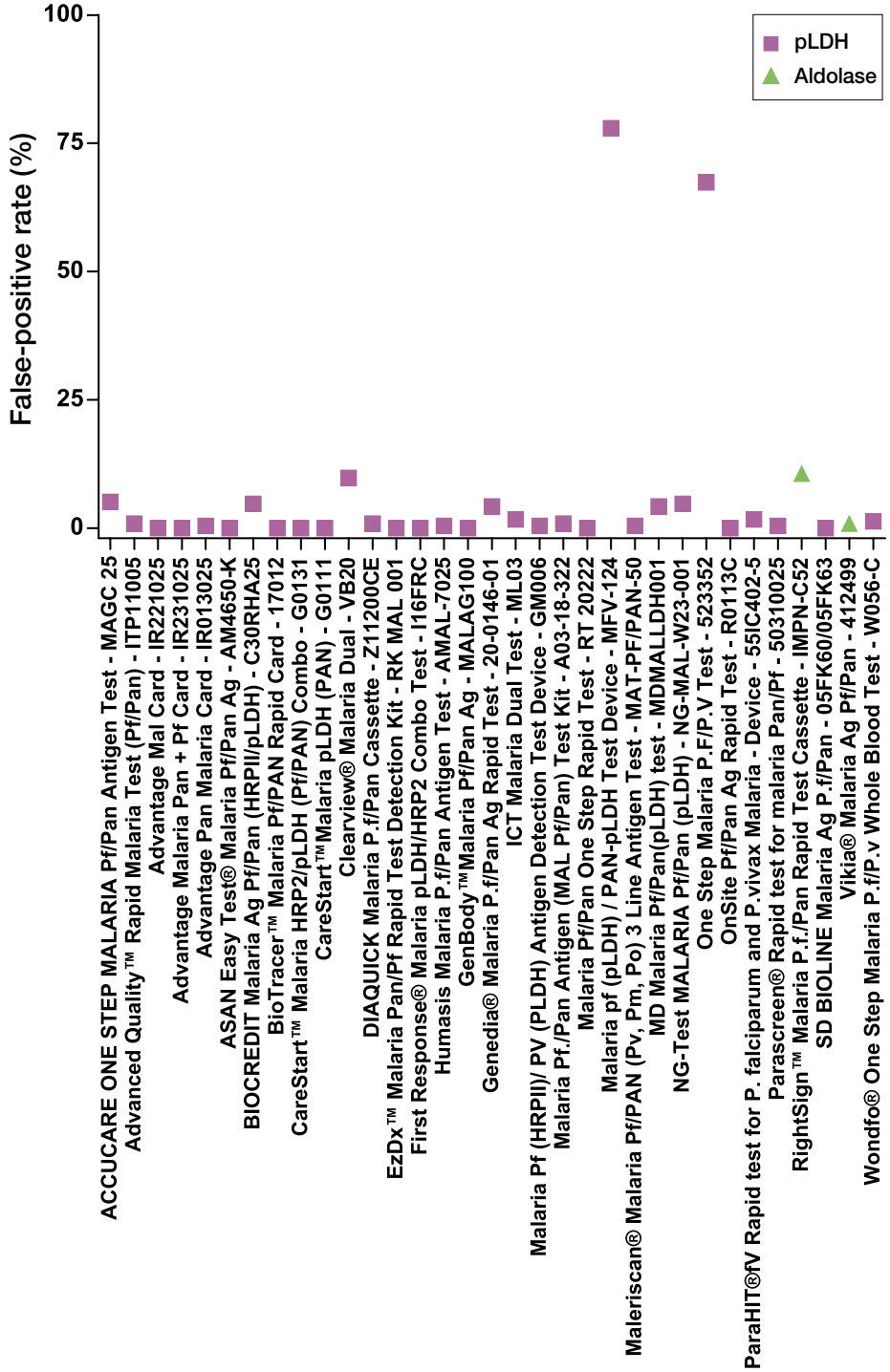


[a] Phase-2 evaluation panel consisted of 100 *Plasmodium* spp.-negative samples, of which 59 were clean negatives from healthy volunteers with no known current illness or blood abnormality.

particularly those containing rheumatoid factor and human anti-mouse antibody. There were, however, only 13 samples containing non-*Plasmodium* infectious agents and 29 samples containing immunological factors. For detailed information on the blood abnormalities and pathogens that generated false-positive results in specific products, see Annex 4 (tables A4.8 and A4.9).

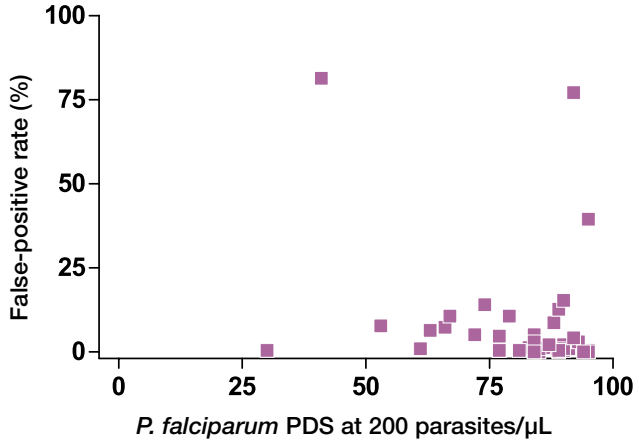
Importantly, there was no clear trend of higher false-positive rates in tests with higher PDS, indicating no clear trade-off between the sensitivity and specificity of the tests at these detection thresholds (Figs 16 and 17).

Figure 15: Phase-2 *Plasmodium* spp. (pan or *P. vivax/Pvom* test line) false-positive rate against clean-negatives[a]



[a] Phase-2 evaluation panel consisted of 100 *Plasmodium* spp.-negative samples, of which 59 were clean negatives from healthy volunteers with no known current illness or blood abnormality.

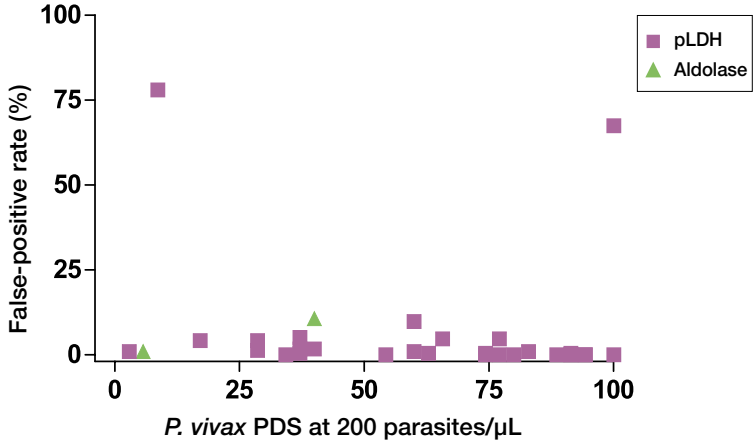
Figure 16: Phase-2 *P. falciparum* false-positive rate[a] versus *P. falciparum* panel detection score (PDS)[b] at low (200) parasite density (parasites/µL)



[a] False-positive rate is for clean-negatives only.

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

Figure 17: 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 for clean-negatives only.

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

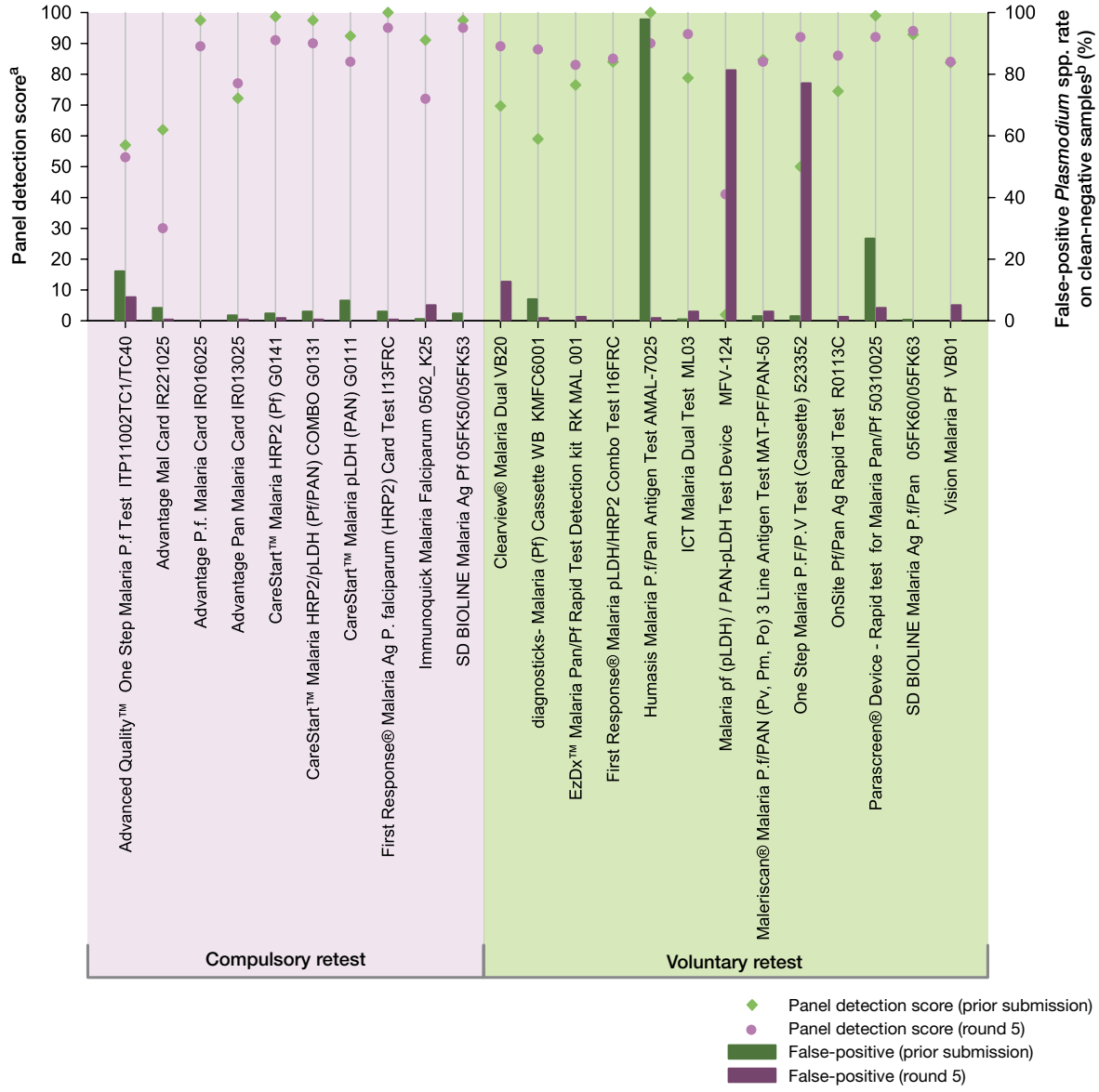
12.4. Performance of products under the compulsory resubmission requirement

With the new requirement for compulsory resubmission of products within 5 years of testing and the limit of one voluntary submission per manufacturer, over half (55%) of the products in round 5 had been evaluated previously. For 17 (74%) of the resubmissions, this was the second testing, and six had been tested more than twice. Figs 18 and 19 show the performance in first and second testing of products against wild-type *P. falciparum* and *P. vivax* at 200 parasites/µL and clean-negative samples that had been resubmitted compulsorily and voluntarily.

For the 10 products that had not been tested since round 1 (compulsory resubmissions), a significant correlation was found between the PDS in rounds 1 and 5 for *P. falciparum* at low density (Spearman rank correlation, $r = 0.92$, $p < 0.001$). The median change in PDS between the two rounds was –7.6% (range, –32.0 to 4.8%), which was significantly different from zero (Wilcoxon signed rank test, $p = 0.013$). As only four of the products detect non-*falciparum* parasites, no statistical analysis was conducted for detection of the *P. vivax* parasite panel.

The change in performance between rounds followed a different pattern for the 13 products that were voluntarily resubmitted for testing. No significant correlation was found in the PDS for *P. falciparum* at lower parasite density in

Figure 18: Phase-2 *P. falciparum* panel detection score[a] at low (200) parasite density (parasites/µL) during initial and subsequent testing of compulsorily and voluntarily resubmitted malaria RDTs

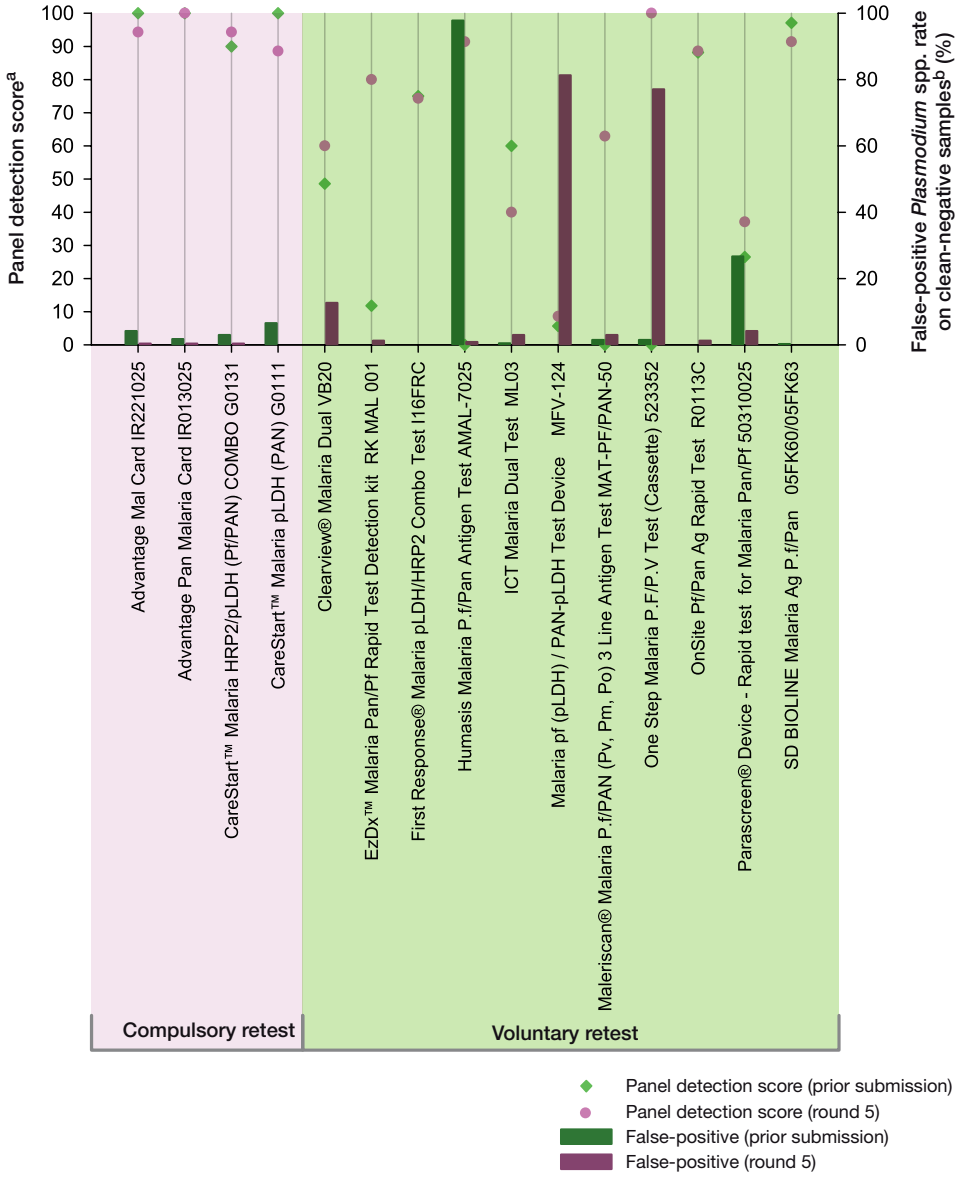


[a] Panel detection score: A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
[b] Clean-negative, blood samples from healthy volunteers with no known current illness or blood abnormality.

consecutive submissions (Spearman rank correlation, $r = 0.32$, $p = 0.29$). The median change in detection of *P. falciparum* was 6.5% (range, –10.0 to 42.0%), which was significantly different from zero (Wilcoxon signed rank test, $p = 0.033$). Most of these products (11/13) detected *P. vivax*, and detection of this parasite improved overall (median change, 10.6%; range, –20.0 to 100.0%), although the change was not statistically significant (Wilcoxon signed rank test, $p = 0.075$). No correlation was found in the PDS against *P. vivax* at a lower parasite density of consecutive submissions (Spearman rank correlation, $r = -0.032$, $p = 0.925$).

Importantly, there was little change in the false-positive rates of the resubmitted products, with four exceptions. The high false-positive rates (> 25%) of two voluntarily resubmitted products in prior testing were reduced to < 5% in round 5, while their ability to detect *P. vivax* was improved, with minimal loss of ability to detect *P. falciparum*. The opposite result was found for another two voluntarily submitted products with low false-positive rates (< 2%) in prior testing, which returned exceptionally high false-positive rates (> 75%) in round 5. These changes were associated with a higher PDS for *P. falciparum* at a lower density and mixed results for *P. vivax* detection.

Figure 19: Phase-2 *P. vivax* panel detection score[a] at low (200) parasite density (parasites/µL) during initial and subsequent testing of compulsorily and voluntarily resubmitted malaria RDTs



[a] Panel detection score: A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
[b] Clean-negative, blood samples from healthy volunteers with no known current illness or blood abnormality.

13. HEAT STABILITY

A single *P. falciparum* culture sample (from the same lot as tested in rounds 3 and 4) was used as the reference sample to test heat stability. This was necessary because establishment of a continuous in vitro culture system for *P. vivax* is very difficult, largely because of the selective invasion of reticulocytes by the parasite. Therefore, 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 and through the WHO-FIND lot-testing programme during product selection for procurement of RDTs.

All the *P. falciparum*-only RDT test lines were heat-stable. Thus, they detected a cultured *P. falciparum* sample the same number of times when stored at room temperature (< 25 °C) or at 35 °C or 45 °C (75% humidity) for 2 months (Fig. 20).

Overall, the products were more stable against samples with high (2000 parasites/µL) rather than low (200 parasites/µL) parasite density (Figs 21, 23, 25 and 27 and Figs 20, 22, 24 and 26, respectively), as little deterioration will not be apparent at high parasite density. The stability of pan-pLDH-detecting test lines was much poorer than that of HRP2-detecting test lines, at both high and low parasite density.

Most combination test products have pan lines that poorly detect low-density *P. falciparum* samples at baseline. Furthermore, tests with a baseline positivity < 100% showed unpredictable variation in positivity rates on subsequent testing, indicating that they were on the borderline of visibility. One of the two combination tests with good baseline pan line reactivity to the low-density sample showed a marked reduction in performance after 2 months at 35 °C or 45 °C. Some combination *P. falciparum* test lines were stable at 35 °C but lost the ability to detect antigen after incubation at 45 °C.

As reported previously, a few products showed better performance after incubation (Figs 21, 22, 24, 26, 27).

The results of heat and thermal stability testing are summarized in Table 6, and detailed results are presented in Annex 4 (tables A4.11–A4.13a) and in Figs 20–27, which show the results for the two lots combined (maximum score, 30; 15 tests per lot against 200 parasites/µL; maximum score, 10; 5 tests per lot against 2000 parasites/µL).

Table 6: Heat stability testing results for 42 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate after 60 days at baseline (room temperature) and after incubation at 35 °C and 45 °C[a]

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 Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	28.0	29.0	27.0	NA	NA	NA	10.0	8.0	8.0	NA	NA	NA
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
IMMUNOQUICK® MALARIA falciparum	0502_K25	BIOSYNEX	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Pf and pan														
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	25.0	22.0	3.0	1.0	3.0	0.0	10.0	10.0	10.0	7.0	9.0	3.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	26.0	29.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	7.0	10.0	8.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	30.0	30.0	30.0	24.0	28.0	8.0	10.0	10.0	10.0	10.0	10.0	10.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	30.0	30.0	29.0	0.0	16.0	0.0	9.0	10.0	10.0	9.0	10.0	10.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	30.0	29.0	27.0	0.0	0.0	20.0	10.0	10.0	10.0	10.0	10.0	10.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	30.0	30.0	29.0	28.0	26.0	16.0	10.0	10.0	10.0	10.0	10.0	10.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	30.0	30.0	30.0	0.0	3.0	1.0	10.0	10.0	10.0	9.0	9.0	10.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	30.0	30.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	8.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	30.0	30.0	30.0	0.0	0.0	1.0	10.0	10.0	10.0	10.0	10.0	10.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	30.0	30.0	30.0	0.0	3.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	30.0	30.0	28.0	0.0	0.0	0.0	10.0	10.0	10.0	5.0	10.0	1.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	30.0	30.0	13.0	1.0	0.0	4.0	10.0	10.0	10.0	0.0	0.0	0.0
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	9.0	9.0	9.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	3.0	2.0	0.0	3.0	1.0	0.0	10.0	10.0	10.0	10.0	10.0	9.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	30.0	30.0	29.0	0.0	0.0	0.0	10.0	9.0	10.0	10.0	9.0	10.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	14.0	17.0	20.0	4.0	28.0	30.0	10.0	10.0	10.0	6.0	10.0	10.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	30.0	30.0	30.0	0.0	2.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	30.0	30.0	30.0	0.0	0.0	1.0	10.0	10.0	10.0	9.0	10.0	10.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	30.0	30.0	30.0	3.0	1.0	4.0	10.0	10.0	10.0	10.0	10.0	10.0

(continued)

Table 6: Heat stability testing results for 42 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate after 60 days at baseline (room temperature) and after incubation at 35 °C and 45 °C[a] *(continued)*

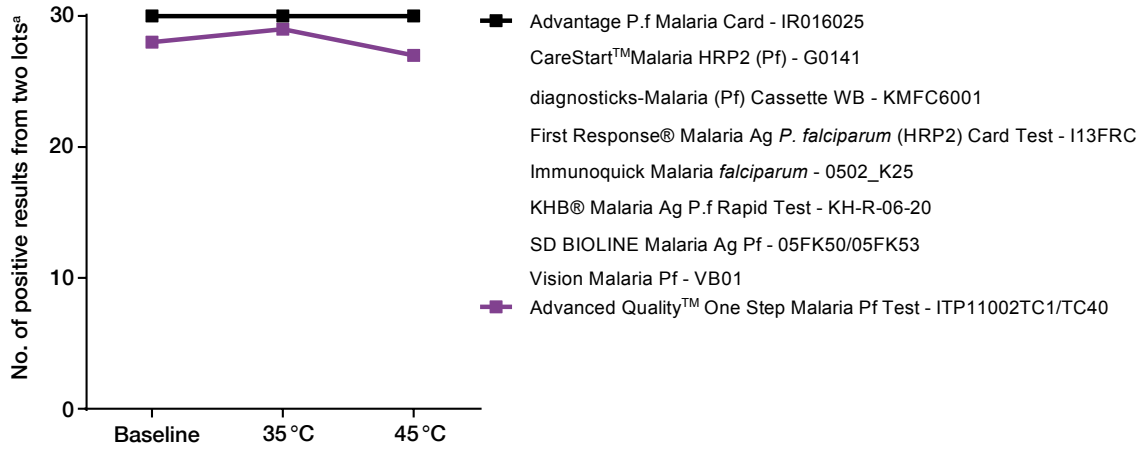
Product	Catalogue number	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (pan line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (pan line)		
			200 parasites/µL			200 parasites/µL			2000 parasites/µL			2000 parasites/µL		
			Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C	Baseline	35 °C	45 °C
			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 30) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined			Number of tests positive (max. 10) Lots 1 and 2 combined		
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	30.0	30.0	30.0	0.0	6.0	30.0	10.0	10.0	10.0	10.0	6.0	10.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	30.0	30.0	30.0	0.0	0.0	0.0	10.0	10.0	10.0	10.0	10.0	10.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	30.0	29.0	29.0	0.0	0.0	0.0	10.0	10.0	10.0	6.0	6.0	0.0
Pf and Pv/Pvom														
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	30.0	29.0	19.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	25.0	27.0	25.0	NA	NA	NA	10.0	9.0	7.0	NA	NA	NA
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	30.0	29.0	29.0	NA	NA	NA	10.0	10.0	9.0	NA	NA	NA
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	30.0	29.0	28.0	NA	NA	NA	10.0	10.0	10.0	NA	NA	NA
Pan only														
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	11.0	20.0	18.0	NA	NA	NA	10.0	10.0	9.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	NA	NA	NA	30.0	30.0	30.0	NA	NA	NA	10.0	10.0	10.0

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

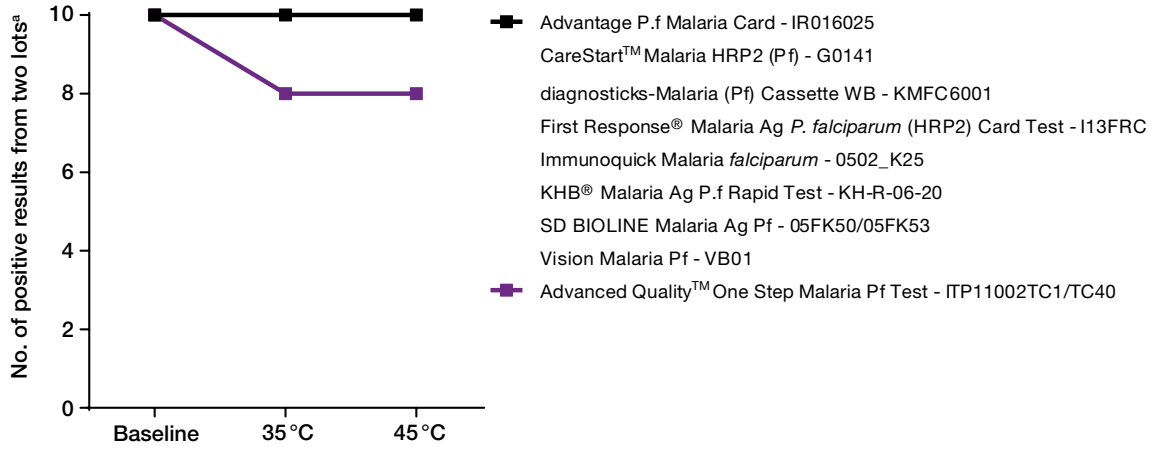
[a] Positive results presented in the table are based on stability of a positive reader 1 result

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



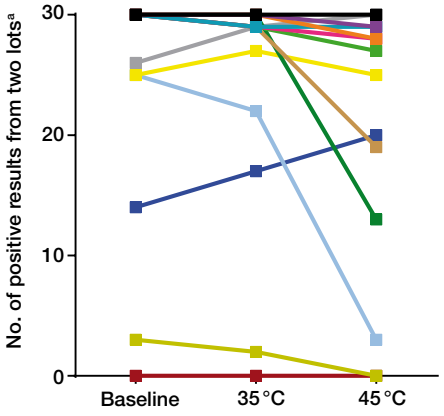
[a] Maximum score is 30 (15 tests x 2 lots)

Figure 21: Heat stability of *P. falciparum*-specific test line of *P. falciparum*-only 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);

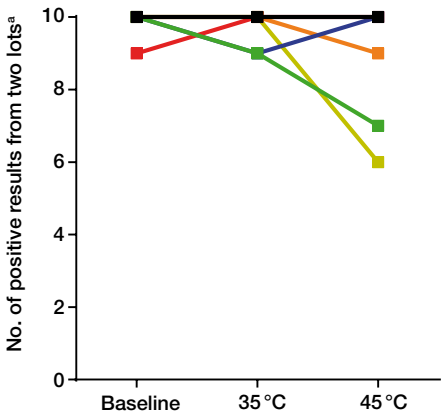
Figure 22: Heat stability of *P. falciparum*-specific test line in combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Advantage Malaria Pan + Pf Card - IR231025
- Clearview® Malaria Dual - VB20
- EzDx™ Malaria Pan/Pf Rapid Test Detection Kit - RK MAL 001
- First Response® Malaria pLDH/HRP2 Combo Test - I16FRC
- ICT Malaria Dual Test - ML03
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
- MD Malaria Pf/Pan(pLDH) test - MDMALLDH001
- NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
- One Step Malaria P.F/P.V Test - 523352
- OnSite Pf/Pan Ag Rapid Test - R0113C
- Parascreen® Rapid test for malaria Pan/Pf - 50310025
- RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
- BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo - G0131
- DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
- Malaria Pf/Pan One Step Rapid Test - RT 20222
- GenBody™ Malaria Pf/Pan Ag - MALAG100
- ParaHIT® fV Rapid test for *P. falciparum* and *P.vivax* Malaria - Device - 55IC402-50
- Vikia® Malaria Ag Pf/Pan - 412499
- Wondfo® One Step Malaria P.f/P.v Whole Blood Test - W056-C
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- ASAN Easy Test® Malaria Pf/Pan Ag - AM4650-K
- Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
- Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
- Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
- ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
- Advantage Mal Card - IR221025

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

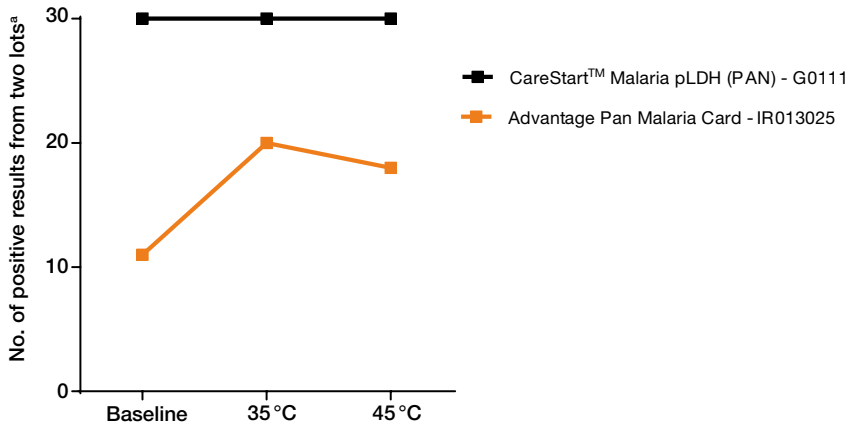
Figure 23: Heat stability of *P. falciparum*-specific test line in combination tests against a high-density *P. falciparum* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
- Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
- Advantage Mal Card - IR221025
- Advantage Malaria Pan + Pf Card - IR231025
- ASAN Easy Test® Malaria Pf/Pan Ag - AM4650-K
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo - G0131
- Clearview® Malaria Dual - VB20
- DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
- EzDx™ Malaria Pan/Pf Rapid Test Detection Kit - RK MAL 001
- First Response® Malaria pLDH/HRP2 Combo Test - I16FRC
- GenBody™ Malaria Pf/Pan Ag - MALAG100
- Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
- Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
- MD Malaria Pf/Pan(pLDH) test - MDMALLDH001
- NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
- One Step Malaria P.F/P.V Test - 523352
- OnSite Pf/Pan Ag Rapid Test - R0113C
- Parascreen® Rapid test for malaria Pan/Pf - 50310025
- RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
- Vikia® Malaria Ag Pf/Pan - 412499
- Wondfo® One Step Malaria P.f/P.v Whole Blood Test - W056-C
- BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- ParaHIT® fV Rapid test for *P. falciparum* and *P.vivax* Malaria - Device - 55IC402-50
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
- Malaria Pf/Pan One Step Rapid Test - RT 20222
- ICT Malaria Dual Test - ML03
- Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006

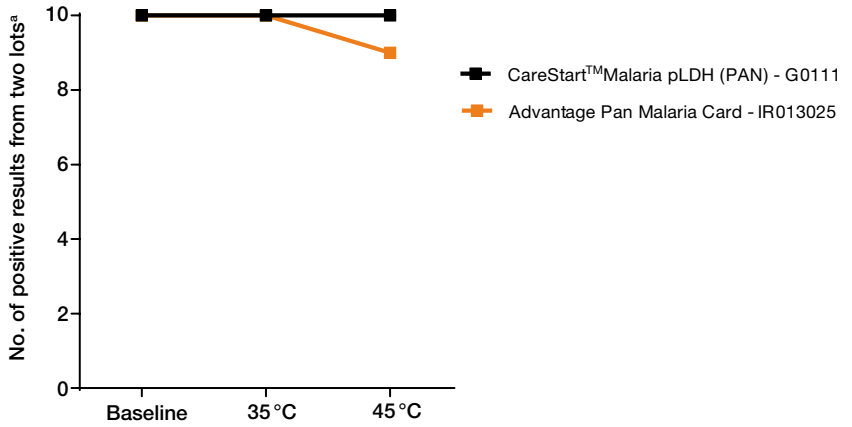
[a] Maximum score is 10 (5 tests x 2 lots)

Figure 24: 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.



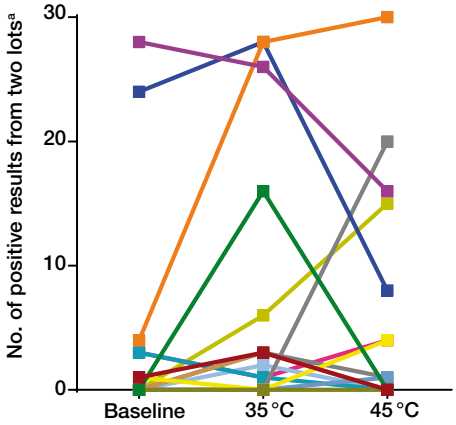
[a] Maximum score is 30 (15 tests x 2 lots)

Figure 25: Heat stability of pan line of pan-specific tests against a high-density (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



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

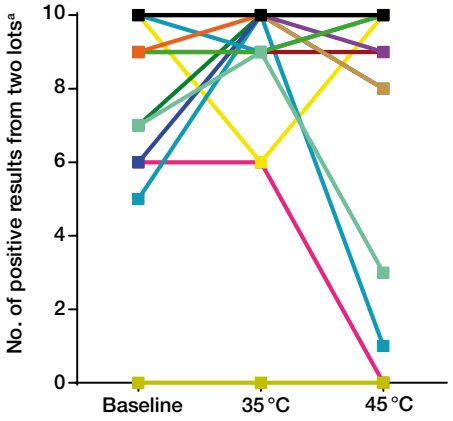
Figure 26: Heat stability of pan line of combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Advantage Malaria Pan + Pf Card - IR231025
- CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo - G0131
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
- ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
- Clearview® Malaria Dual - VB20
- EzDx™ Malaria Pan/Pf Rapid Test Detection Kit - RK MAL 001
- OnSite Pf/Pan Ag Rapid Test - R0113C
- First Response® Malaria pLDH/HRP2 Combo Test - I16FRC
- BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
- Parascreen® Rapid test for malaria Pan/Pf - 50310025
- NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
- Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
- Advantage Mal Card - IR221025
- DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
- GenBody™ Malaria Pf/Pan Ag - MALAG100
- ICT Malaria Dual Test - ML03
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- Malaria Pf/Pan One Step Rapid Test - RT 20222
- MD Malaria Pf/Pan(pLDH) test - MDMALLDH001
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
- Vikia® Malaria Ag Pf/Pan - 412499

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

Figure 27: 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.



- Advantage Mal Card - IR221025
- Advantage Malaria Pan + Pf Card - IR231025
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo - G0131
- EzDx™ Malaria Pan/Pf Rapid Test Detection Kit - RK MAL 001
- First Response® Malaria pLDH/HRP2 Combo Test - I16FRC
- Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
- MD Malaria Pf/Pan(pLDH) test - MDMALLDH001
- NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
- Parascreen® Rapid test for malaria Pan/Pf - 50310025
- SD BIOLINE Malaria Ag P.f/Pan - 05FK60/05FK63
- BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- OnSite Pf/Pan Ag Rapid Test - R0113C
- Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
- Malaria Pf/Pan One Step Rapid Test - RT 20222
- Clearview® Malaria Dual - VB20
- Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
- DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
- ICT Malaria Dual Test - ML03
- Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
- ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
- RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
- GenBody™ Malaria Pf/Pan Ag - MALAG100
- Vikia® Malaria Ag Pf/Pan - 412499
- Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01

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

14. EASE-OF-USE DESCRIPTION AND RDT ANOMALIES

After becoming proficient in using a product, two technicians produced a joint agreed assessment of product usability. The results, which are a description of the product with emphasis on aspects considered important for ease of use in the field, are presented in Table 7. It is important to note that the assessment does not include a comparison of blood transfer devices, which are critical to both the safety and the accuracy of the testing procedure and pose a significant challenge to many users. These may vary for manufacturers with many products. Procurement decisions should be based on which transfer devices are best suited for the intended users, and this should be discussed with the manufacture before procurement. It is strongly recommended that RDT packaging, contents, safety and ease of use be assessed in the field as part of the product selection process (Annex S2, Table AS2.1).

In round 5, technicians regularly recorded specific observations (or anomalies) based on a list of problems encountered with some production lots evaluated in past rounds of testing and at WHO-FIND lot testing laboratories. Since March 2012, these observations have been included in all WHO-FIND lot testing reports and were recorded as part of product testing for the first time in round 5. Table 8 shows the percentages of products for which anomalies were observed in at least one of the RDTs tested; it does not give the frequency of the observation for a given product. Generally, users should be aware of major anomalies that may be encountered in production lots (Fig. AS2.1), as they can affect interpretation of RDT results.

Table 8: Observations on RDT production lots that might affect interpretation of the results

Observations/anomalies	No.(%) of products with at least one recorded observation
Red background	42 (100)
Incomplete clearing	42 (100)
Failure to flow	26 (61.9)
Shift or misplacement of strip	10 (23.8)
Ghost lines	7 (16.7)
Diffuse test lines	2 (4.8)
Patchy broken test line	2 (4.8)

Table 7: Ease-of-use description of 42 malaria RDTs included in round 5: 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	Format	Language of instruction	Items included in package[c]
			Mixing wells involved	Retractable needle	Strip exposed	Score (max.3)	No diagram	Diagram of result (1)	Diagram of result & method (2)	Score (max.2)							
Pf only																	
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	1	1	1	3	–	–	X	2	5	1	15	Capillary tube	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	1	0	1	2	–	X	–	1	3	1	20	Loop	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	1	0	0	1	–	–	X	2	3	1	15	None	Dipstick	English	Test tube, buffer, alcohol swab, lancet, dessicant (no colour indicator)
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	1	1	1	3	–	–	X	2	5	1	15	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	1	0	1	2	–	–	X	2	4	1	15	Inverted cup	Cassette	English, French	Buffer, alcohol swab, lancet, dessicant (colour indicator)
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
Pf and pan																	
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	None
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	1	0	1	2	–	–	X	2	4	1	15	Capillary tube	Cassette	English	None
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	1	0	1	2	–	–	X	2	4	1	30	Capillary tube	Cassette	English	None
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	1	0	1	2	–	–	X	2	4	1	20	Loop	Cassette	English	None
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	1	0	1	2	–	–	X	2	4	1	25	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	1	0	1	2	–	–	X	2	4	1	20	Loop	Cassette	English, German	None
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	None
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
GenBody™ Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	1	0	1	2	–	X	–	1	3	1	30	Loop	Cassette	English	None
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	1	1	1	3	–	–	X	2	5	1	15	Loop	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	1	0	1	2	–	–	X	2	4	1	30	Loop	Cassette	English, French, Spanish	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	1	0	1	2	–	–	X	2	4	1	30	Inverted cup	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)

Table 7 *(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	Format	Language of instruction	Items included in package[c]
			Mixing wells involved	Retractable needle	Strip exposed	*Score* (max. 3)	No diagram	Diagram of result (1)	Diagram of result & method (2)	*Score* (max. 2)							
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	1	0	1	2	–	–	X	2	4	1	30	None	Cassette	English	None
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	None
Malaria pf-LDH/PAN-LDH Antigen Test Device	MFV-124	AZOG, INC.	1	0	1	2	–	–	X	2	4	1	20	None	Cassette	English	None
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	1	0	1	2	–	–	X	2	4	1	30	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	1	0	1	2	–	–	X	2	4	1	30	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	1	0	1	2	–	–	X	2	4	1	30	Loop	Cassette	English	None
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	1	0	1	2	–	X	–	1	3	1	20	Loop	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	1	0	1	2	–	–	X	2	4	1	10	Pipette	Cassette	English	None
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	1	0	1	2	–	–	X	2	4	1	15	Inverted cup	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	Danish, English, French, German, Greek, Italian, Polish, Portuguese, Spanish, Swedish	None
Pf and Pv/Pvom																	
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	1	0	1	2	–	–	X	2	4	1	30	Loop	Cassette	English	None
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (colour indicator)
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1	0	1	2	–	–	X	2	4	1	15	None	Cassette	English	None
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	1	1	1	3	–	–	X	2	5	1	25	Capillary tube	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	1	0	1	2	–	–	X	2	4	1	15	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
Pan only																	
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	1	0	1	2	–	–	X	2	4	1	20	Pipette	Cassette	English	Buffer, alcohol swab, lancet, dessicant (no colour indicator)

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[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 results=1; diagram of result and method=2

[c] These are items in addition to the test device and blood transfer device and are not necessarily standard contents. Procurers should verify what materials accompany test kits with the manufacturer and ensure they procure all the required accessories at the same time.

15. 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 can greatly improve the management of febrile illness in malaria-endemic areas. To be useful in this context, they must have adequate:

- sensitivity, to detect nearly all clinically significant cases of malaria;
- specificity, to accurately discriminate non-malarial febrile illness from malaria, to ensure appropriate management and accurate disease monitoring;
- stability, to maintain accuracy after transport and storage in ambient conditions; and
- ease-of-use and safety, to allow safe, correct preparation and accurate interpretation of results.

Malaria RDTs were evaluated in terms of these four major requirements in order to assist national malaria control programmes and other procurement agencies in selecting products appropriate for their needs. The panel used allowed successful discrimination between the RDTs evaluated, which had a considerable range of performance. A number of products showed a high rate of antigen detection combined with a low false-positive rate and good heat (thermal) stability. These attributes are essential if the tests are to be relied upon as a basis for decisions about malaria treatment in most endemic populations.

Overall, the mean product PDS against low-density *P. falciparum* samples in round 5 was 81.0%, consistent with the results of round 4 (81.6%) and suggesting that performance may be plateauing after several rounds of improvement.[1] For *P. vivax,* the mean PDS of 61.3% is the highest achieved.[2] The median false-positive rate was 1.3%, which is comparable with that in previous rounds; however, in rounds 4 and 5, a limited number of products returned exceptionally high false-positive rates. Overall, a high level of performance has been maintained in *P. falciparum*-only tests and improved performance in *P. vivax*-detecting RDTs.

Ten products tested in round 1 of the programme were resubmitted for testing in round 5. The performance of most of the products was comparable 5 years after the initial testing; only one that had previously fulfilled the WHO procurement criteria no longer does. Another product showed improved performance and fulfilled the WHO procurement criteria when it previously did not.

The 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 the accuracy of RDTs in a specific epidemiological context in the hands of the 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 with control for confounding factors and is calibrated to a level likely to discriminate differences in the performance of various products. The discussion points described below should therefore be taken into account in interpreting the results.

15.1. Panel detection score and its relation to sensitivity

Evaluation of the RDTs against the phase-2 wild-type parasite panel with a parasite density of 200 parasites/µL (Figs 10 and 11) revealed a wide range of frequency and consistency of antigen detection between products, recorded as the PDS. As expected, testing at higher parasite density (2000 or 5000 parasites/µL) resulted in smaller differences in performance. As two tests from two different lots were tested at 200 parasites/µL and as all four results had to be positive in order for a sample to be considered *detected* by an RDT, a positive result indicated the ability of a product to detect the target antigen in the sample and to do this consistently (both tests from both lots). A parasite density of about 200 parasites/µL should be detected to ensure high field sensitivity for clinically significant malaria infection in many malaria-endemic populations (*9*).

The PDS in the panels used in this evaluation differs from the test sensitivity in clinical settings for five main reasons.

(i) The performance of different lots or batches of the same product may vary. Variation in lot performance is an issue for all diagnostics; therefore, the results found in the evaluation may not predict the results for subsequent RDT lots. It is important to test lots before their distribution in the field to ensure that the expected performance is maintained (section 15.2).

(ii) In clinical settings, patients show wide variation in parasite density, the range depending on the local epidemiology of the disease. The parasite density in the population tested affects the clinical sensitivity of a test. The PDS against a test panel of blood samples diluted to 200 parasites/µL is likely to underestimate the clinical sensitivity of an RDT in areas where symptomatic patients have much higher parasite densities. Many tests that show 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 at 2000 parasites/µL. **The small differences in PDS seen in** Figs S1, S2 and 9–11 and Tables 4 and 5 **found among the better-performing RDTs in this evaluation are unlikely to result in noticeable differences in clinical sensitivity,**

[1] PDS for *P. falciparum* in rounds 1, 2 and 3 was 67.2%, 69.9%, 75.5%, respectively.

[2] PDS for *P. vivax* in rounds 1, 2, 3 and 4 was 36.0%, 58.9%, 47.1% and 51.3%, respectively.

and other issues, such as stability, cost, experience and training of the intended users, ease of use (Annex S2) and manufacturing capacity may be equally important factors in test selection. Consideration of the parasite density in target populations and the probable sensitivity of RDTs in the field indicates that, even in areas with high transmission and strong malaria immunity, the population may include individuals with a low parasite density but clinically significant infection (e.g. young children, pregnant women, people who regularly use bed nets, immigrants and people with reduced immunity). The ability to detect low parasite-density infections reliably, therefore, remains important. As some countries move towards elimination of malaria, population immunity will decrease and/or clinical cases may be detected earlier, and it will become increasingly important to use diagnostic tests that detect low parasite density (i.e. with a high PDS against samples with 200 parasites/µL).

(iii) The performance of tests against the challenge panel may not always predict sensitivity in clinical testing, e.g. when antigen expression by certain parasite populations differs greatly from that in the panel. For example, *P. falciparum* strains in some areas of India and South America do not express HRP2 antigens because of gene deletions (*10*, *11*). If a significant proportion of parasites in a given area do not express HRP2 and HRP3, tests to detect other target antigens (e.g. pLDH or aldolase) must be used. To date, parasite populations with a high frequency of non-expression of target antigens have not been identified elsewhere than South America.[1]

(iv) The conditions under which RDTs are transported and stored can alter their sensitivity in the field. The tests evaluated in round 5 were shipped and stored under conditions intended to safeguard them from degradation by high temperature or other extreme conditions. If such precautions are not taken with purchased RDTs, loss of performance could result. The ambient temperature of storage conditions varies widely in the settings in which these tests are commonly used, as does the temperature during transport; therefore, the requirements for the heat stability of a product will differ. Tests should be transported and stored well within the temperature range recommended by the manufacturer and extremes of temperature avoided (*31*, *32*).

(v) Diagnostic sensitivity and specificity depend on the quality of preparation and interpretation of the tests. Highly trained technicians tested all the products in this evaluation. In clinical settings, malaria RDTs are often used by health workers with limited training and supervision; therefore, simple design and clearly interpretable results are required to ensure translation of the technical proficiency of a product into accurate diagnoses in the field (*33*).

15.2. False-positive rate and specificity

False-positive rates are reported against a panel of 59 clean-negative samples taken from blood donated in low-transmission settings by people without symptoms of malaria. In addition, false-positive rates were calculated with a smaller number of samples with specific characteristics that affect the likelihood of a false-positive result from an immunodiagnostic test (e.g. rheumatoid factor, anti-nuclear antibody) or that may be significant in a specific population in a malaria-endemic area (e.g. leishmaniasis, dengue). The importance of these results depends on the intended area of use. High false-positive rates with samples of blood from dengue patients, for example, might not be a significant factor in regions in which dengue does not occur. In view of the small number of samples in each category in this evaluation, the **results should be considered primarily a guide to potential cross-reactions, which should be closely monitored if they are 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 the choice of one product over another. Overall, in this evaluation, there was no correlation between a lower PDS (loss of sensitivity) and a low false-positive rate (high specificity). A number of products had both a high PDS and a low false-positive rate.

15.3. Reactivity of combination HRP2 and pan-pLDH test lines against *P. falciparum* samples

Instructions for the use of *P. falciparum*/pan and pan/*P. falciparum* combination tests classify *P. falciparum* infections as either HRP2 test line-positive alone or in combination with the pan-pLDH line. Combination tests that return only a positive HRP2 test line may be incorrectly interpreted as false-positives for malaria infection secondary to persistent (HRP2) antigenaemia. The results in this report clearly indicate that most combination tests in which HPR2 is used for the detection of *P. falciparum* return positive results only on the HRP2 band at lower densities of *P. falciparum* (Table A4.2). When both the HRP2 and the pan test bands were positive, the mean band intensity was significantly lower on the pan test band than on the HRP2 test band. Therefore, it is important to reinforce adherence to the manufacturer's instructions for use (Annex 2) and to emphasize that for combination HRP2/pan-pLDH tests, a HRP2 test line-positive alone, may well be attributed to the poor reactivity of pan-pLDH lines.

[1] Cheng Q, Gatton M, Barnwell J, et al. *Plasmodium falciparum* parasites lacking histidine-rich protein 2 and 3: a review and recommendations for accurate reporting. Acceptedfor publication.

15.4. Heat (thermal) stability

The RDTs evaluated were held for 2 months at room temperature (< 25 °C) and at 35 °C and 45 °C at 75% humidity and tested to evaluate stability at these temperatures. The importance of thermal stability depends on the conditions under which a product will be transported and stored. Thus, stability at high temperatures is vital if an RDT is to be stored at clinics in a country where the ambient temperature can reach 45 °C in the hot season but is less critical in a high-altitude or cooler environment where the temperature rarely rises above 35 °C. Many commercially available RDTs indicate 30 °C or 40 °C as the maximal storage temperature. Higher temperatures were tested in this evaluation because malaria-endemic countries often have maximum ambient temperatures of 35 °C, although use of cool storage can allow storage of products below this temperature. When RDTs are likely to be transported and stored at high ambient temperatures, heat (thermal) stability must be considered a significant factor in ensuring sensitivity.

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

A limitation of our evaluation is that we can assess only the stability of test lines to detect cultured *P. falciparum* samples. Several products showed high stability at the temperatures and times used in the evaluation. In general, in this round, as in previous ones, pan-specific lines (pLDH) performed less well at baseline and were less stable than HRP2 test lines, so that it was difficult to assess post-incubation stability.

While the temperature and humidity were held constant in this evaluation, temperatures in the field fluctuate with the time of day and season. Two months' storage at a set temperature cannot accurately predict long-term stability under field conditions, but loss of sensitivity for parasite detection over this period indicates that significant sensitivity will be lost if RDTs are stored at similar or higher temperatures for a significant amount of their storage time and the likelihood of greater susceptibility to degradation during short exposure to much higher temperatures, such as during transport (*34*, *35*).

15.5. Ease-of-use description and RDT anomalies in production lots

The sensitivity and specificity of RDTs depend on the quality of preparation and interpretation. 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 dipstick format (*36*). The extra cost of this format may be offset by the advantages of greater accuracy and, in some cases, less additional equipment required to perform them.

The method by which blood is transferred from the patient to the test is important for the safety of the user and for the accuracy of the volume transferred. Devices for blood transfer are supplied with RDTs and vary widely in design and accuracy (*30*). The performance of blood transfer devices was not formally assessed in this evaluation, as blood was transferred from a tube with a micro-pipette to ensure that the volume specified by the manufacturer was used. **Procurement programmes for RDTs should consider the adequacy of the blood transfer device supplied, including the experience of health workers and the cost and time required for retraining.** It may be appropriate to discuss with manufacturers the possibility of changing the blood transfer device from that usually supplied.

The clarity of results is important for interpreting tests. A clearly visible (intense) test line is less likely to be overlooked than a line that is barely visible. While reading proficiency and adequate workplaces should be ensured, some health workers might have suboptimal vision or work in inadequate lighting. The intensity of the line of the test band was found to be closely associated with the PDS achieved by RDTs (tables A4.2 and A4.3).

The importance of format and the simplicity of the test design depend on the intended users. Trained laboratory technicians can handle a complicated procedure more reliably than village volunteers with limited supervision. In all cases, 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 user (*37*, *38*). Annex S2 provides guidance on conducting a field-based ease-of-use assessment (Table AS3.1).

In the production lots submitted for evaluation, anomalies that affected interpretation of the results were encountered with variable frequency. On the basis of the experience of several rounds of product testing, with 2700 lots tested in the WHO-FIND lot testing programme, a glossary of RDT anomalies has been prepared (Figure AS2.1). This glossary may be used in RDT training programmes to illustrate potential problems with some production lots and how to report them accurately. As many of the anomalies are infrequent, they might not be picked up in manufacturers' quality control or lot release procedures; therefore, this information is also useful for manufacturers that wish to improve their processes.

15.6. Inter-lot variation

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

Inter-test variation, which is also seen, will be detected to some extent by routine lot testing. Ensuring that manufacturers follow good manufacturing standards should minimize the likelihood of inconsistencies due to poor practice in the manufacturing process. Culture-based panels[1] that are subsets of the phase-1 panel used in this evaluation are available as reference standards for manufacturers against which to set their lot-release criteria.

15.7. Target antigens and species

The malaria RDTs assessed 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 that target the different antigens in this evaluation. While the products with the highest PDS for *P. falciparum* targeted HRP2, a number of pLDH-detecting products had high PDS against *P. vivax*. The thermal stability of tests that target these different antigens also overlapped for samples with high parasite density.

The choice of RDT should take into account the target antigen: HRP2-detecting RDTs should not be used in areas where non-expression of HRP2 is common (*10*, *11*). Tests that detect only HRP2 (without pLDH or aldolase lines) will be of limited use where non-*falciparum* malaria is common. pLDH (and possibly aldolase) RDTs may have further advantages when 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. As mentioned in section 14.3, however, combination tests with both HRP2 and pan test lines should not be used for discriminating between acute infection and persistent antigenaemia, as the overall reactivity of pan test lines is much lower than that of HRP2 test lines, particularly at low parasite density.

The required sensitivity of a test may also vary by species: a less sensitive test may be more acceptable for detection of *P. vivax* than for *P. falciparum*, as severe outcomes due to missed diagnoses are less likely. Use of a sufficiently sensitive pan-specific-only test may be appropriate in areas where both *P. falciparum* and *P. vivax* occur, if all infections are to be managed initially as *P. falciparum* infections with artemisinin-based combination therapy, but species-specific monitoring data would be lost. Tests with high PDS for both *P. falciparum* and *P. vivax* were found in this and previous rounds of product testing (*3–6*).

Pan-species tests were not evaluated for detection of *P. ovale* or *P. malariae* in this evaluation because of lack of sources of suitable mono-species infections with these parasites. Published data suggest that the sensitivity of RDTs for detecting these species is significantly poorer than for *P. falciparum* and *P. vivax* (*39*).

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

16. USING RESULTS TO ENSURE HIGH-QUALITY DIAGNOSIS IN THE FIELD

This report provides data to guide malaria control programmes in selecting products that are likely to perform to a high standard in the context in which the programme operates. Final product selection requires that these data be considered systematically, taking into context the distribution of parasite density in the target population in whom the tests will be used and the experience and training of the intended users. Box 3 lists WHO's minimum RDT selection criteria, as endorsed by the Malaria Policy Advisory Committee, and tables S2, and 5 are colour-coded to reflect these minimum performance criteria for product selection. A web-based tool for filtering product testing results by various parameters is available and maintained by FIND.[1] Furthermore, an algorithm to guide selection is given in Annex S3, and detailed guidance was published by WHO in *Good practices for selecting and procuring rapid diagnostic tests for malaria* (*13*) and *Universal access to malaria diagnostic testing* (*14*).

While malaria RDTs can be used in a number of settings, the greatest impact on public health will be brought about by extending access to accurate, parasite-based diagnoses of malaria to regions and populations where good-quality microscopy-based analysis is impractical to maintain. This will allow implementation of recent WHO recommendations on universal parasite-based diagnosis before antimalarial therapy (*2*) and currently applies to most people at risk for 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, so that health systems can reduce wastage of antimalarial medicines and focus on appropriate management of non-malarial causes of fever, including early pneumonia and sepsis. A successful RDT programme must therefore address not only malaria but also the management of other common and severe febrile illnesses that occur locally in the differential diagnosis of malaria if an RDT programme is to have its full potential public health impact.

16.1. Beyond procurement

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

This report provides information to guide procurement of RDTs within this framework. Factors beyond the performance characteristics reported here, however, must influence procurement decisions. An example of an algorithm, including an ease-of-use assessment, is provided to guide decisions in annexes S2 and S3.

Details of implementation will vary widely between programmes, depending on local capacity and needs. Further recommendations on budgeting, planning and implementation can be found in Annex 5 and in the relevant WHO guidance document (*14*).

16.2. Lot testing

As a complement to product testing, WHO and FIND currently support laboratories that perform continued 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 before purchase or, when they arrive in a country, before dispersal to the field and for clinical use. Testing is performed against parasite-positive and -negative panels prepared and characterized in the same way as the panels used in this evaluation. A number of national institutions have also developed this capacity. Lot testing reassures countries that the product they have purchased performs to a high standard before distribution and helps to ensure that manufacturers produce consistently good lots and improve their products.

Countries and manufacturers ship 100–150 RDTs to regional, WHO-recognized lot testing centres, where they are evaluated against a small panel of parasites at high and low density and against negative samples (Figure 2). They are subsequently incubated at a temperature close to the manufacturer's specified storage temperature and retested after 18 months. Initial results are available after 5 days, and definitive results after subsequent retesting. Details of the protocol can be found in the methods manual for lot testing *(25)*. National malaria programmes and procurement 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.

[1] *http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp*. An interactive guide designed to short-list tests according to programme needs, based on the performance of tests in rounds 2–5 of the WHO product testing programme, can be found at: *http://www.finddiagnostics.org/programs/malaria-afs/malaria/rdt_quality_control/product_testing/interactive-guide/index.jsp* (accessed 27 May 2014).

17. CONCLUSIONS

This report adds to the large data set on malaria RDT performance published annually since 2009 (*3–6*). The product-testing programme continues to be an authoritative source in the field of malaria RDT evaluations in terms of the number of products evaluated and its comprehensiveness. New laboratory methods have been developed and validated to support parasite characterization, and this work has generated new findings on variation in antigen content at similar parasite densities and in the structure and expression of HRP proteins. Publication of the results of past WHO product testing rounds has affected the procurement practices of countries and procurement agencies and contributed to a shift in the malaria RDT market towards better-performing products (*1*). The report of round 5 adds to the number of well-performing RDTs for which comprehensive performance data are now available and provides updated data on 23 products resubmissions.

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ANNEXES

Annex S1: Characteristics of evaluation panels used in rounds 1–5 of WHO malaria RDT product testing, 2008–2013

Currently, the basis for diagnosing malaria with antigen-detecting RDTs is the detection in a patient's blood of one or more target malaria antigens, including HRP2 (*P. falciparum* only), pLDH (*Plasmodium* spp.(pan-pLDH), *P. falciparum* (Pf-pLDH), non-*falciparum* (Pv-pLDH, Pvom-pLDH) and aldolase (all *Plasmodium* spp). The antigen concentration in samples with the same parasite density varies. Therefore, the concentrations of malaria antigens in the samples that comprise evaluation panels must be consistent in successive rounds of WHO malaria RDT product testing to ensure that the results of each round are highly comparable (statistically equivalent).

Therefore, antigen concentrations were quantified in triplicate in all panel samples, including dilution pairs of 200 and 2000 parasites/µL, by quantitative ELISA. Only results that were consistent in the triplicate runs and showed a value factor between the 200 and the 2000 parasites/µL dilutions close to 10 were considered acceptable and eligible for the performance evaluation panel. In some instances, the antigen concentration was below the detection limit of the ELISA, particularly for aldolase, which is present in malaria parasite samples at much lower concentrations than the other two antigens. Samples that gave inconsistent results for more than one of the three antigens were excluded from the panel.

Despite careful standardization of procedures, the tables and figures below show a wide variation in antigen concentrations for the same parasite density. There are a number of possible explanations, including differences in the level of antigen expression by isolates; different durations of infection (accumulating antigens); different parasite growth stages at the time of collection (expressing different levels of antigen); the presence of circulating HRP2 from previous growth cycles; and HRP2 produced by parasites sequestered in the host's vascular tissues that cannot be accounted for in the estimate of parasite density on the blood slide.

Before each round of WHO malaria RDT product testing, the distribution of HRP2, pLDH and aldolase concentrations at 200 parasites/µL dilution of the wild-type *P. falciparum* and wild-type *P. vivax* samples selected for the phase-2 panels were systematically compared with those in the previous round to ensure there was no statistically significant difference. The figures and tables below show the distribution of antigen concentrations in all five performance evaluation panels. No statistically significant differences were seen (Kruskal-Wallis test; $p > 0.15$), confirming that the results of each new round are additive (and comparable) to the previous ones. In the following box and whisker plots, the end of whiskers represent minimum and maximum values; the box represents middle 50% of data and the line through box represents median values; the crosses represent the mean values.

Figure AS1.1: Box-and-whisker plot of distribution of *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wildtype) panels.

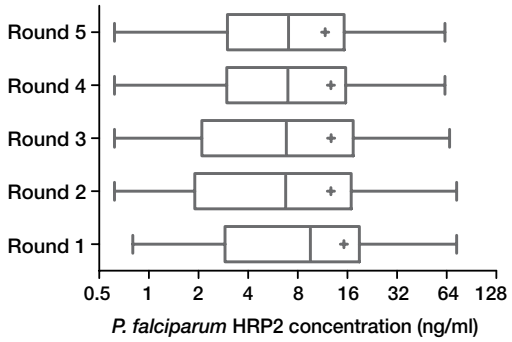


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

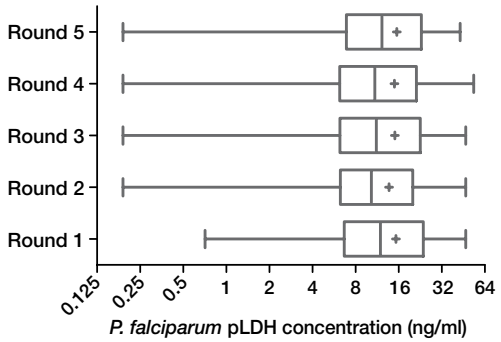


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

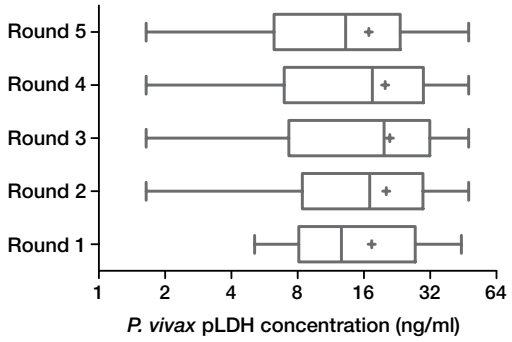


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

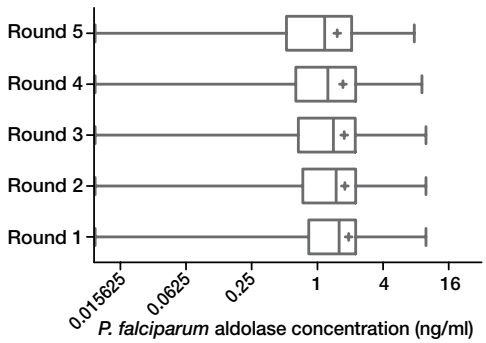


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

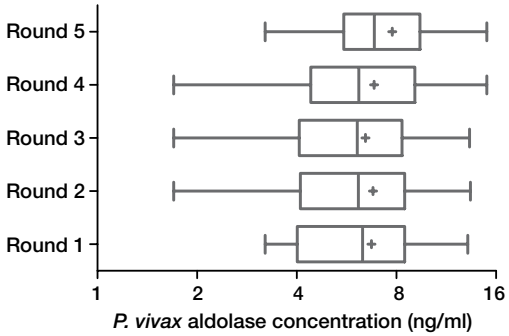


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	78	99	99	98	99
Minimum	0.80	0.62	0.62	0.62	0.62
25% percentile	2.90	1.90	2.10	2.97	3.00
Median	9.57	6.76	6.83	6.98	7.05
75% percentile	18.94	16.91	17.37	15.65	15.31
Maximum	73.70	73.70	66.70	62.48	62.48
Mean	15.28	12.70	12.77	12.72	11.74
Std. Deviation	16.98	15.75	15.19	14.72	13.20

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.2: Statistics for *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	74	93	92	92	94
Minimum	0.71	0.19	0.19	0.19	0.19
25% percentile	6.68	6.27	6.23	6.20	6.90
Median	11.95	10.31	11.18	10.92	12.24
75% percentile	23.75	20.10	22.70	21.28	23.05
Maximum	47.15	47.15	47.15	53.53	43.02
Mean	15.31	13.71	15.08	14.97	15.53
Std. Deviation	11.47	10.90	11.72	11.98	11.43

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.3: Statistics for *P. vivax* pLDH concentration (ng/mL) in wildtype product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	20	37	33	32	34
Minimum	5.10	1.64	1.64	1.64	1.64
25% percentile	8.10	8.40	7.30	6.96	6.26
Median	12.65	17.00	19.78	17.50	13.22
75% percentile	27.40	29.69	31.89	29.84	23.42
Maximum	44.40	47.90	47.90	47.90	47.90
Mean	17.38	20.24	20.99	20.00	16.84
Std. Deviation	11.57	13.27	13.55	13.00	12.59

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.4: Statistics for *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	77	98	99	98	99
Minimum	0.00	0.00	0.00	0.00	0.00
25% percentile	0.84	0.74	0.67	0.63	0.52
Median	1.61	1.49	1.40	1.25	1.17
75% percentile	2.25	2.25	2.23	2.25	2.07
Maximum	9.90	9.90	9.90	9.08	7.74
Mean	1.93	1.79	1.76	1.72	1.52
Std. Deviation	1.73	1.66	1.69	1.68	1.52

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Table AS1.5: Statistics for *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5
Number of values[a]	20	40	34	33	35
Minimum	3.21	1.70	1.70	1.70	3.21
25% Percentile	4.02	4.11	4.07	4.41	5.55
Median	6.33	6.15	6.10	6.16	6.86
75% Percentile	8.47	8.47	8.32	9.10	9.43
Maximum	13.15	13.40	13.30	15.00	15.00
Mean	6.73	6.81	6.45	6.86	7.78
Std. Deviation	2.89	3.15	2.90	3.23	3.30

[a] The number of values is the number of samples for which consistent ELISA results were obtained.

Annex S2: Malaria RDT field assessment and anomalies

The purpose of this assessment, on a limited number of RDTs, is to assess aspects of packaging, safety and ease-of-use and not to evaluate diagnostic accuracy.

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

Obtain malaria parasite-negative blood samples, and where readily accessible, parasite-positive blood samples for testing against RDTs.

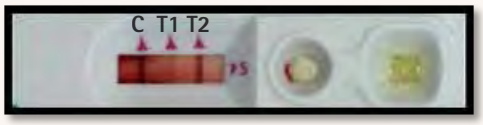
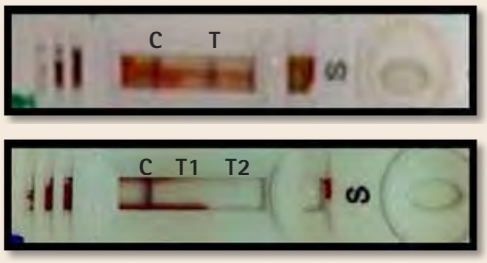
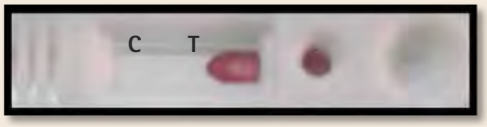
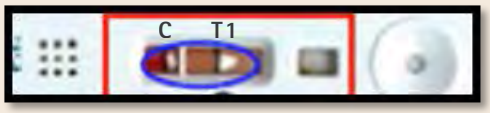
Table AS2.1: Field assessment of RDT packaging, safety and ease-of-use to guide product selection

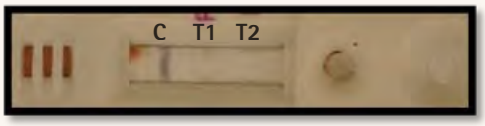
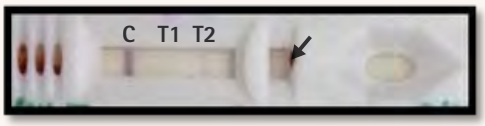
Date of assessment				
Commercial name				
Catalogue number				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed pouches				
The correctly indicated number of RDTs are in the box				
A desiccant is included in each individual RDT pouch				
An expiry date is visible on each RDT pouch				
All required accessories are included in the correct quantities (RDT, buffer, blood transfer device, alcohol swab, lancet, gloves, test tubes (for dipsticks, only)				If no, what is not included:
Instructions				
Instructions are included				
Instructions are in the national language(s)				
The instructions are for the correct product				
The instructions include figures displaying all possible interpretations of the RDT results				
The text and figures are accurate and consistent (specifically order of test lines and results interpretation)				
Preparation and procedure				
The test pouch is easy to open				
It is easy to write on the test device				
The test lines on the device are clearly labelled				
It is easy to use the device for blood collection				
It is easy to open the buffer bottle or ampoule				
The buffer bottle or ampoules have sufficient volume for testing all RDTs in the box				
The buffer bottle or ampoule dispenses even drops				
It is easy to fill the sample well correctly with the provided blood transfer device				
It is easy to fill the buffer well correctly (no overflow)				
The buffer and sample flow well along the test strip				
Result interpretation				
Control and test lines				
Control line is clear				
Test line(s) are clear				
Good clearance of blood by time of reading				If no, number of tests in the box affected:
Steps and reading time				
Reading time <30 min				
Two or fewer timed steps				
Was one or more of the last 10 tests you performed invalid (no control line)?				
If YES, how many?				
Safety				
Are there mixing wells (risk of blood splash)?				
Retractable needle for finger prick?				
Is the RDT in a cassette format (unexposed strip)?				
Have waste disposal safety concerns been addressed? (If no, please describe)				

Figure AS2.1 illustrates examples of RDT observations/anomalies encountered and routinely recorded during Round 5 of WHO Malaria RDT Product Testing at the CDC. In most cases, these anomalies do not invalidate the results, as reactivity in the control and test line areas are still visible, but they may pose challenges to health workers interpreting the results. Furthermore, they should be reported to manufacturers.

An expanded list of notable observations concerning RDT packaging, kit accessories (buffer vials, desiccants) and instructions for use, is under development for use in both product testing and lot testing activities of the WHO-FIND Malaria RDT Evaluation Programme.

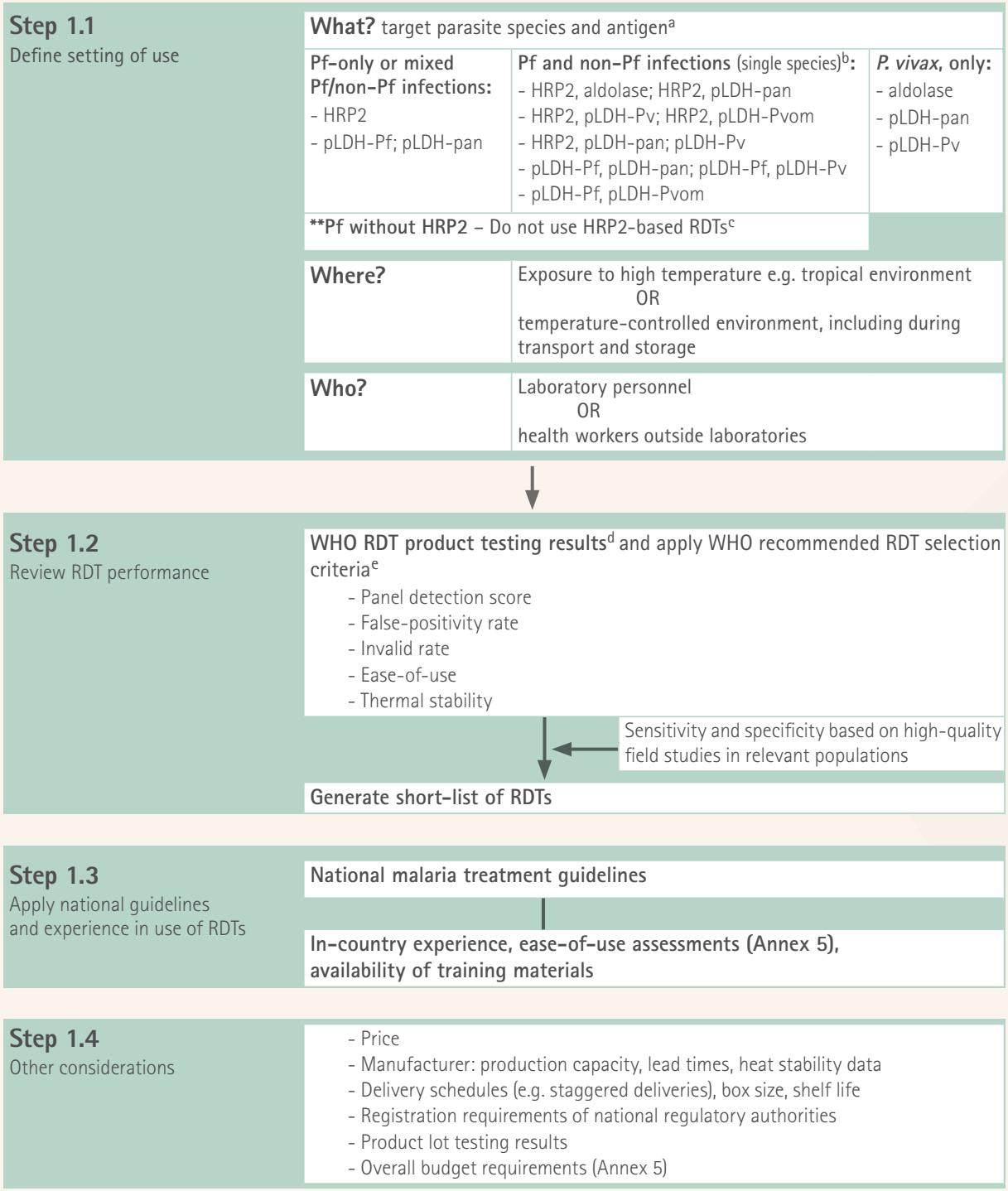
Figure AS2.1: Malaria RDT anomalies encountered in production lots

a) Observations on the test strip		
Red background		Background staining is relatively common. In this example, the result is positive as test lines are positive; however, a more intense red background may obscure weak positive test lines, giving false-negative results
Incomplete clearing		Poor clearing of blood may obscure weak positive test lines, giving false-negative results. In this example, the result is positive as the test line is visible
b) Observations of flow problems		
Failure to flow		Blood and buffer did not run the length of the strip
Irregular migration that obscures test line(s)		One portion of the nitrocellulose near the test band was not absorptive and remained dry during wicking, creating irregular migration of blood/buffer with red background that may obscure test line.
Irregular migration		One portion of the nitrocellulose near the test band was not absorptive and remained dry during wicking, creating irregular migration of blood/buffer with red background. In this example, the result is positive, as the test line is clearly visible.

c) Observations on test lines		
Ghost test lines		*White lines on a stained background. In this example, the result is negative, as the test line is not dark and is thus not visible.*
Patchy broken test line(s)		*The test line is visible but interrupted (broken).*
Diffuse test line(s)		*Test line wider than control, without clearly defined edge.*
d) RDT structural problems		
Strip misplaced in the cassette		*Strip can be seen only partially in the results window.*
Specimen pad not seen in sample window		*Normally, the colour of the conjugated antibody can be seen in the sample window (commonly purple, pink or blue).*

Annex S3: Selection of an appropriate RDT

Figure AS3.1: How to select of an appropriate RDT



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

[b] Tests with a *P. falciparum*-specific line and pan-specific line will not distinguish *P. falciparum*-only infections from mixed *P. falciparum* infections. Distinguishing *P. falciparum* from mixed *P. falciparum-vivax* infections is important only 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 (e.g. Pf-Pv-pan-pLDH) to detect these increases the complexity of test interpretation. A programme should prioritize these various advantages and disadvantages according to local conditions in the initial stage of making procurement decisions.

[c] *P. falciparum* parasites lacking HRP2 +/- HRP3 genes have been identified with high frequency in parts of South America *(10)*.

[d] See references *(3–6)*.

[e] WHO RDT procurement criteria : http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/ (accessed 26 June 2014).

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 reference *(13)*.

Annex 1: Characteristics of RDTs evaluated in round 5

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	Required volume (µL) of whole blood	Buffer drops (µL)	Minimum time to results[c] (min)	Maximum reading time (min)	Results Interpre-tation[d] (type A–J)	Format type[e]	Recom-mended storage tempera-ture	Shelf-life (months)
Access Bio. Inc.	CareStart™ Malaria pLDH (PAN)	G0111	P	pan(pLDH)	P	pan(pLDH)	–	5	2	20	–	B	A	1 - 40 °C	–
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	2	20	–	C	A	1 - 40 °C	–
	CareStart™ Malaria HRP2 (Pf)	G0141	F,P	HRP2	P	HRP2	–	5	2	20	–	A	A	1 - 40 °C	–
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	20	30	C	A	4 - 30 °C	18
Artron Laboratories Inc.	Malaria Pf/Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	30	–	C	A	2 - 30 °C	–
ASAN Pharmaceutical Co., Ltd	ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	F,V,O,M	VOM(pLDH), HRP2	P	VOM(pLDH)	HRP2	5	4	30	–	H	A	1 - 30 °C	–
AZOG, INC.	Malaria pf-LDH/PAN-LDH Antigen Test Device	MFV-124	F,P	pan(pLDH), F(pLDH)	P	pan(pLDH)	F(pLDH)	5	2	20	–	C	A	4 - 30 °C	–
Bhat Bio-Tech India (P) Ltd.	Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	F,V,O,M	VOM(pLDH), HRP2	P	VOM(pLDH)	HRP2	5	2	20	–	H	A	2 - 30 °C	24
Bio Focus Co., Ltd.	BioTracer™ Malaria Pf/PAN Rapid Card	17012	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	20	–	C	A	1 - 30 °C	–
BIOSYNEX	IMMUNOQUICK® MALARIA *falciparum*	0502_K25	F	HRP2	P	HRP2	–	20	6	15	–	A	D	2 - 30 °C	–
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F/P.V Test	523352	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2	5	3	15	20	E	A	4 - 30 °C	–
CTK Biotech Inc.	OnSite Pf/Pan Ag Rapid Test	R0113C	F,P	pan(pLDH), HRP2	P	HRP2	pan(pLDH)	5	2	30	–	D	A	2 - 30 °C	18
DIALAB GmbH	DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	20	30	C	A	2 - 30 °C	–
GenBody Inc.	GenBody™ Malaria Pf/Pan Ag	MALAG100	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	30	–	C	A	1 - 30 °C	–
Genomix Molecular Diagnostics Pvt. Ltd.	Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	F,V	HRP2, V(pLDH)	P	HRP2	V(pLDH)	5	3	20	–	F	A	2 - 26 °C	18
Green Cross Medical Science Corp. (Korea)	Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	15	30	C	A	1 - 40 °C	–
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2	5	4	15	30	E	A	4 - 30 °C	–
Hangzhou Biotest Biotech Co. Ltd.	RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	F,P	aldolase, HRP2	P	aldolase	HRP2	5	3	10	20	C	A	2 - 30 °C	–
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	30	–	C	A	1 - 30 °C	–
ICT INTERNATIONAL	ICT Malaria Dual Test	ML03	F,P	pan(pLDH), HRP2	P	HRP2	pan(pLDH)	5	5	30	–	D	A	4 - 30 °C	24
IMACCESS S.A.S	Vikia® Malaria Ag Pf/Pan	412499	F,P	aldolase, HRP2	P	HRP2	aldolase	5	5	20	30	D	A	2 - 30 °C	–
InTec Products, Inc.	Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	3	15	20	C	A	2 - 30 °C	–
	Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/ TC40	F	HRP2	P	HRP2	–	5	3	15	20	A	A	2 - 30 °C	–
J. Mitra & Co. Pvt. Ltd.	Advantage Mal Card	IR221025	F,P	pan(pLDH), F(pLDH)	P	pan(pLDH)	F(pLDH)	5	5	20	20	C	A	4 - 30 °C	24
	Advantage Malaria Pan + Pf Card	IR231025	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	5	20	20	C	A	4 - 30 °C	24
	Advantage Pan Malaria Card	IR013025	P	pan(pLDH)	P	pan(pLDH)	–	5	5	20	20	B	A	4 - 30 °C	24
	Avantage P.f Malaria Card	IR016025	F	HRP2	P	HRP2	–	5	5	20	20	A	A	4 - 30 °C	24
LAB-CARE Diagnostics (India) PVT. LTD.	ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	3	20	–	C	A	2 - 30 °C	24
Medical Diagnostech (Pty) Ltd	MD Malaria Pf/Pan(pLDH) test	MDMALLDH 001	F,P	pan(pLDH), HRP2	P	HRP2	pan(pLDH)	5	4	30	–	D	A	4 - 30 °C	24
SARL NG Biotech, Z.A.	NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	F,P	pan(pLDH), HRP2	P	HRP2	pan(pLDH)	5	4	30	–	D	A	4 - 30 °C	24

(continued)

Annex 1: Characteristics of RDTs evaluated in round 5 *(continued)*

Manufacturer	Product name	Catalogue number	Plasmodium species targeted (F = *P. falciparum* V = *P. vivax* O = *P. ovale* M = *P. malariae* P = pan; major *Plasmodium* species)	Target antigen[a](s)	Sequence and type of bound antibody[b] C	T1	T2	Required volume (µL) of whole blood	Buffer drops (µL)	Minimum time to results[c] (min)	Maximum reading time (min)	Results Interpre-tation[d] (type A-J)	Format type[e]	Recom-mended storage tempera-ture	Shelf-life (months)
Premier Medical Corporation	First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	F	HRP2	P	HRP2	–	5	2	20	–	A	A	1 - 30 °C	24
	First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	2	20	–	C	A	1 - 30 °C	24
RapiGEN INC.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	30	30	C	A	1 - 40 °C	–
Shanghai Kehua Bio-engineering Co.,Ltd.	KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	F	HRP2	P	HRP2	–	5	3	15	30	A	A	4 - 30 °C	24
Span Diagnostics Ltd.	ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2	8	4	25	30	E	A	4 - 40 °C	24
SSA Diagnostics & Biotech Systems	diagnosticks-Malaria (Pf) Rapid Diagnostic Test	KMFC6001	F	HRP2	P	HRP2	–	5	2	20	–	A	A	4 - 45 °C	24
Standard Diagnostics Inc.	SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	F	HRP2	P	HRP2	–	5	4	15	30	A	A	1 - 40 °C	24
	SD BIOLINE Malaria Antigen Pf/Pan	05FK60	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	4	15	–	C	A	1 - 40 °C	24
Orgenics Ltd.(IS)	Clearview® Malaria Dual	VB20	F,P	pan(pLDH), HRP2	P	HRP2	pan(pLDH)	5	5	25	–	D	A	4 - 40 °C	–
Vision Biotech (Pty) Ltd	Vision Malaria Pf	VB01	F	HRP2	P	HRP2	–	5	5	20	–	A	A	4 - 40 °C	–
Zephyr Biomedicals	Parascreen® Rapid test for malaria Pan/Pf	50310025	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2	5	2	20	–	C	A	4 - 30 °C	24
Zhejiang Orient Gene Biotech Co., Ltd.	Malaria Pf/Pan One Step Rapid Test	RT 20222	F,P	pan(pLDH), HRP2	P	HRP2	panpLDH	5	3	20	–	D	A	2 - 30 °C	–

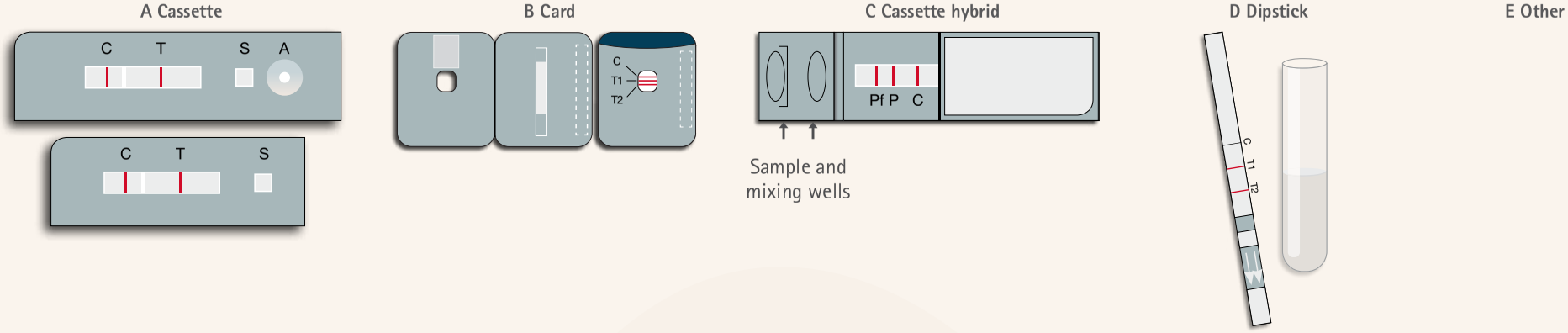
[a] pLDH, plasmodium lactate dehydrogrenase; HRP2, histidine rich protein 2

[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

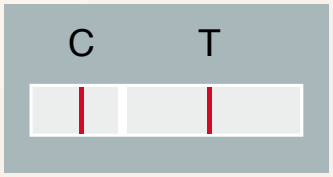
[e] Formats include: cassette (A); card (B); hybrid (C), dipstick (D); or other (E). Each product should ideally be accompanied by all required materials (lancet, pipette, etc.) particularly when used by the village health worker level; however, this is often not the case and the contents depend on the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



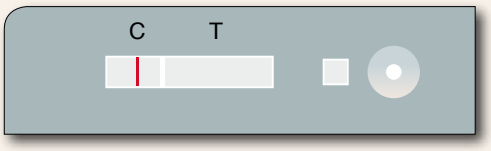
Annex 2: Malaria RDTs: guide to interpretation of results

Type A: Guide to results of generic Pf malaria RDTs

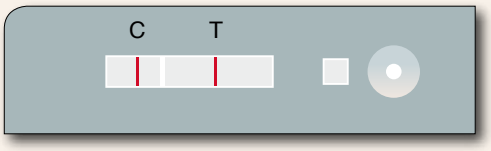
Results window: C=control line; T=test line with bound HRP2 or Pf-specific pLDH antibody.



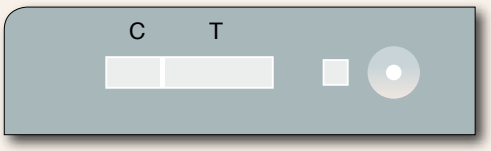
Negative results: One line 'C' appears in the results window.

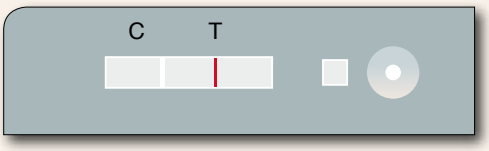


Positive results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window. Test is positive even if the test line is faint.



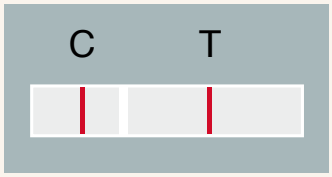
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



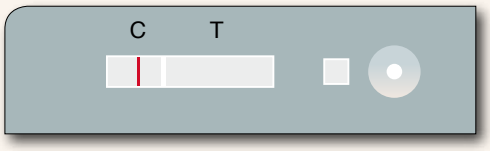


Type B: Guide to results of generic major *Plasmodium* species (pan) malaria RDTs

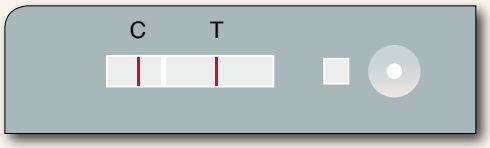
Results window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



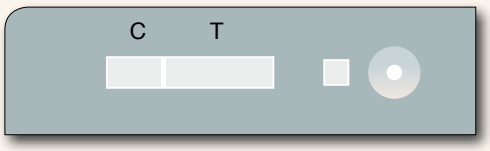
Negative results: One line 'C' appears in the results window.

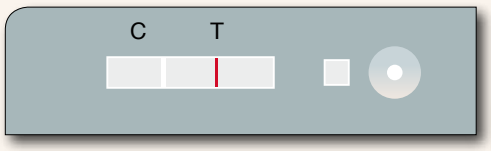


Positive results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



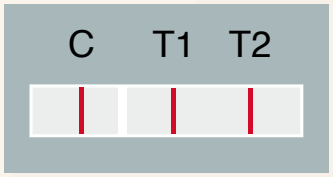
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



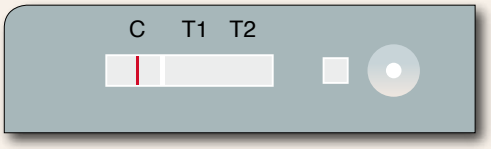


Type C: Guide to results of generic pan-Pf malaria RDTs

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.

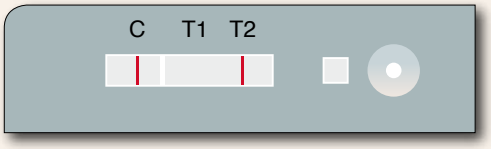


Negative results: Only one line 'C' appears in the results window.

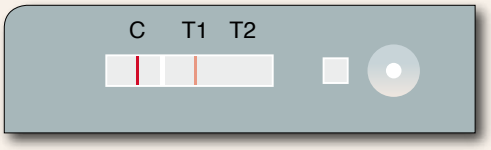


Positive results:

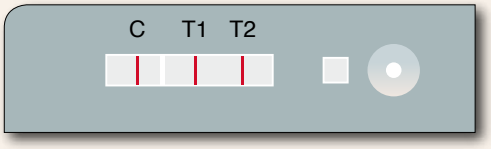
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



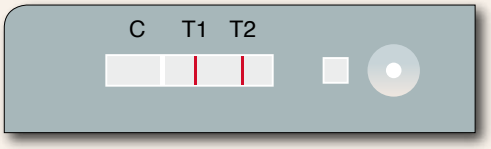
Non-*falciparum* infection (*P. vivax, P. ovale, P. malariae*) or mixed infection:
Two lines 'C' and 'T1" appear in the results window.

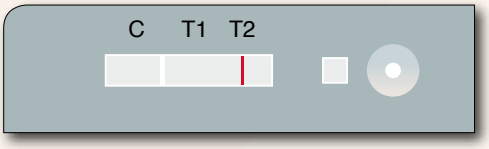


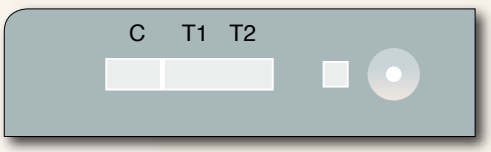
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

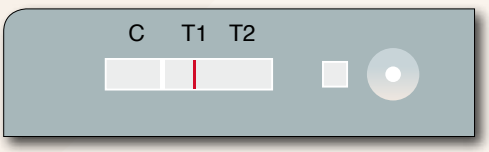


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



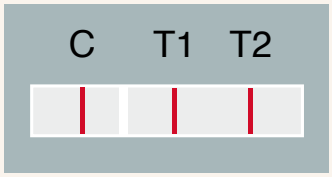




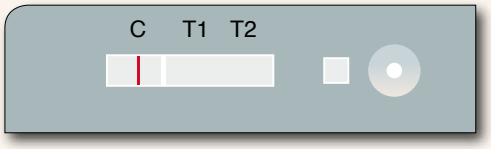


Type D: Guide to results of generic Pf-pan malaria RDTs

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.

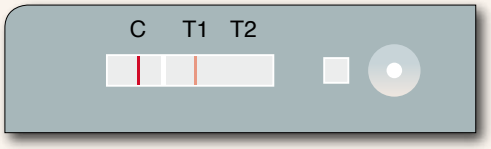


Negative results: Only one line 'C' appears in the results window.

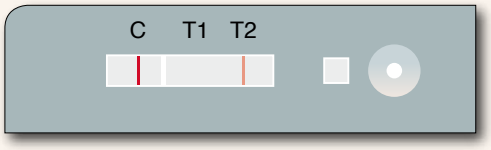


Positive results:

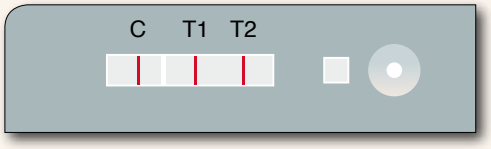
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



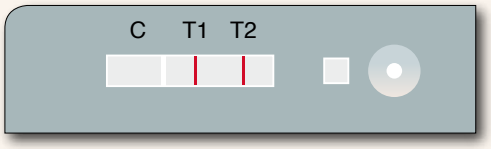
Non-*falciparum* infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection.
Two lines 'C' and 'T2' appear in the results window.

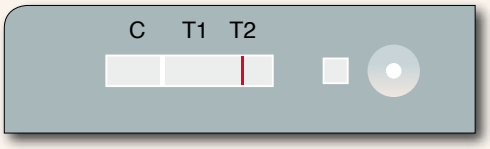


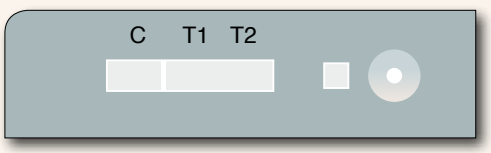
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

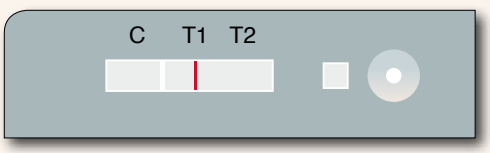


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



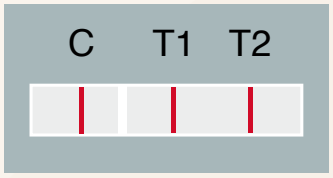




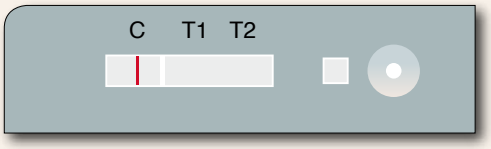


Type E: Guide to results of generic Pv-Pf malaria RDTs

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.

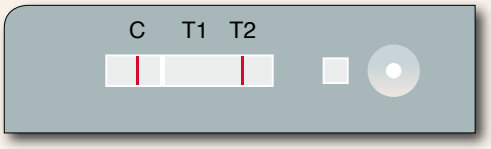


Negative results: Only one line 'C' appears in the results window.

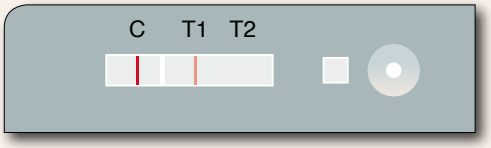


Positive results:

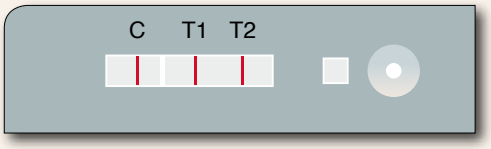
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



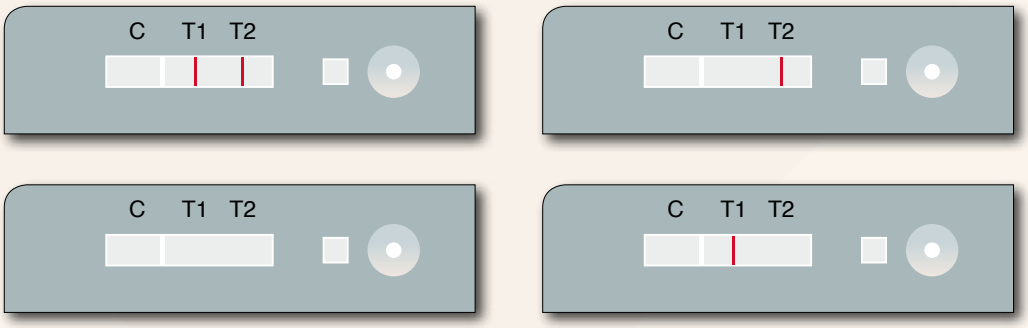
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



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

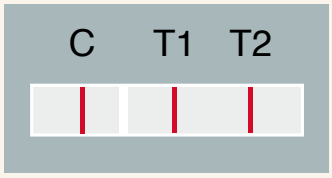


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

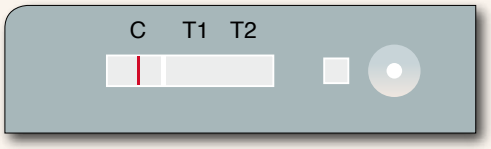


Type F: Guide to results of generic Pf-Pv malaria RDTs

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.

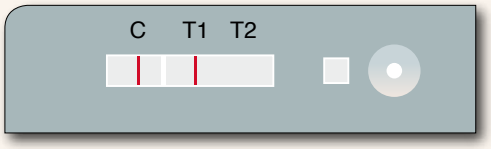


Negative results: Only one line 'C' appears in the results window.

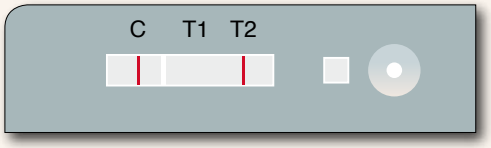


Positive results:

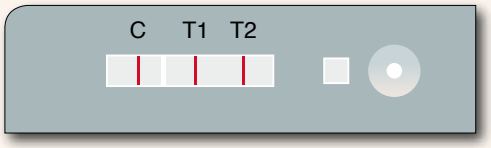
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



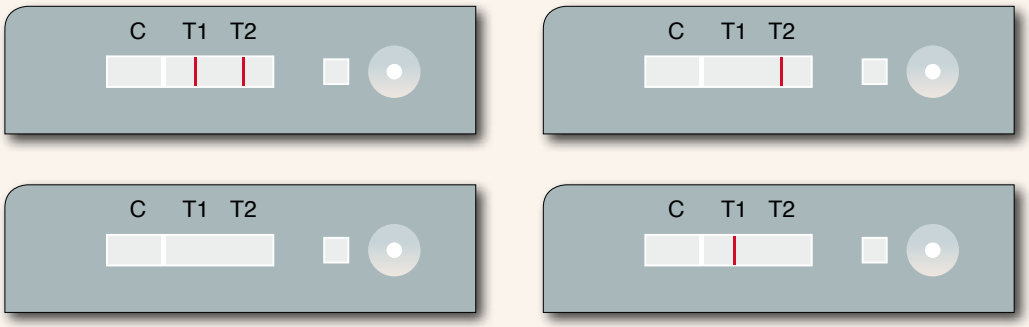
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



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

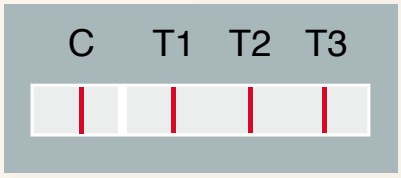


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

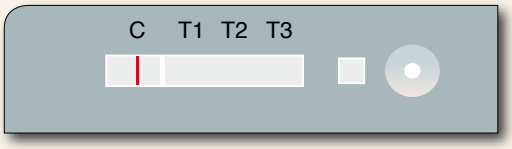


Type G: Guide to results of generic pan-Pv-Pf malaria RDTs

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

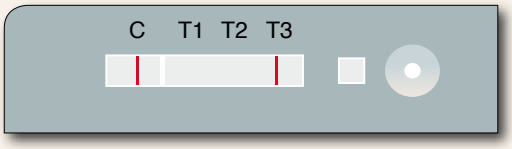


Negative results: Only one line 'C' appears in the results window.

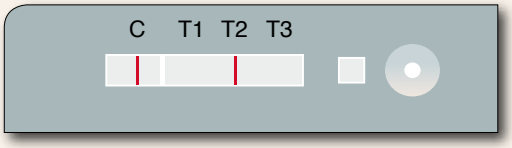


Positive results:

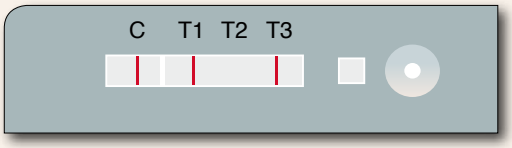
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



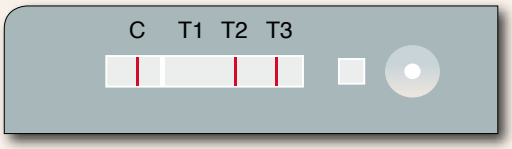
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



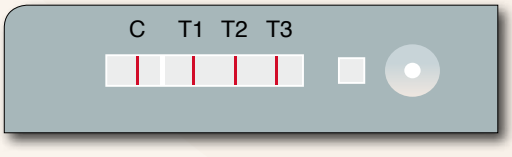
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



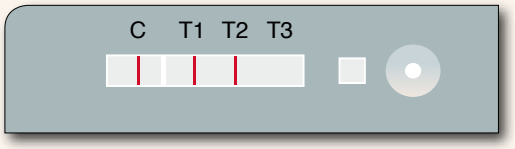
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



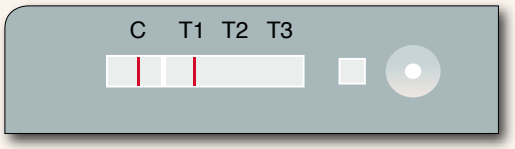
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



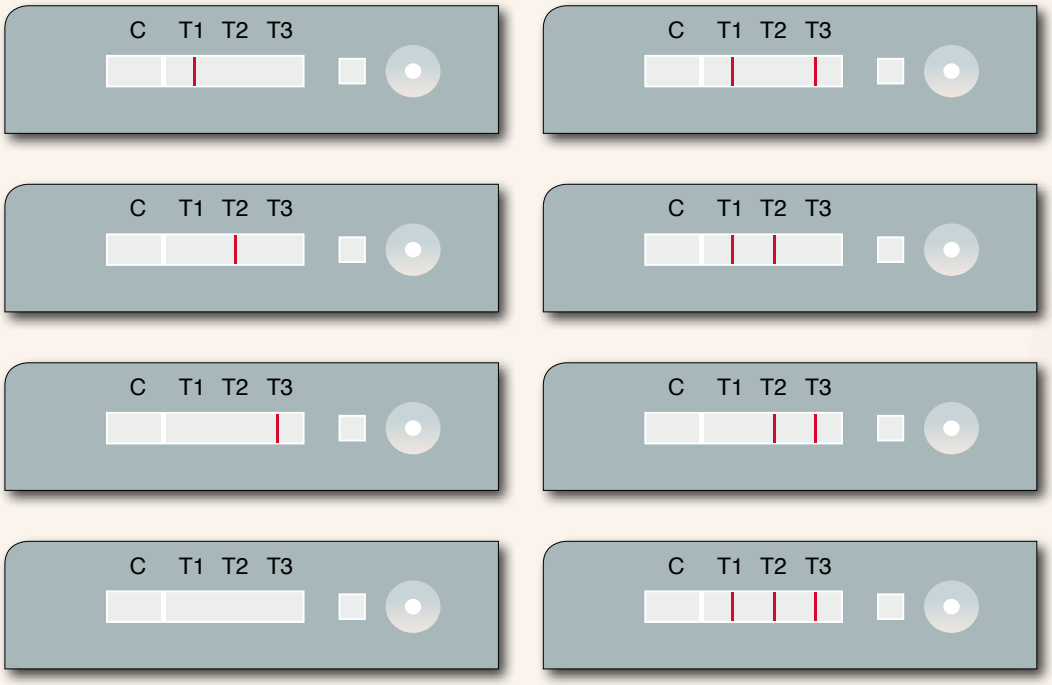
P. vivax with or without *P. ovale* and/or *P. malariae* infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



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

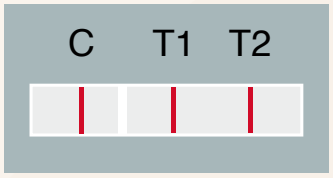


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

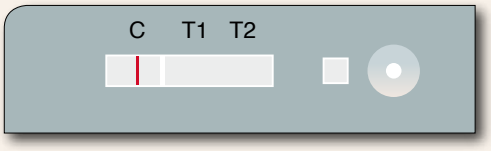


Type H: Guide to results of generic vom[1]-Pf malaria RDTs

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

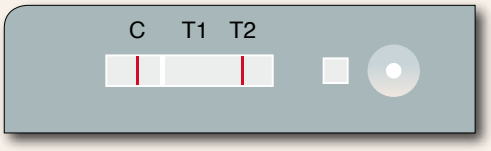


Negative results: Only one line 'C' appears in the results window.

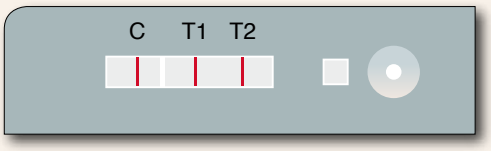


Positive results:

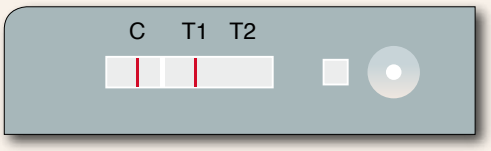
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



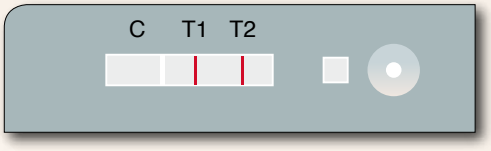
P. falciparum mixed infection (with *P. vivax*, *P. ovale* and/or *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

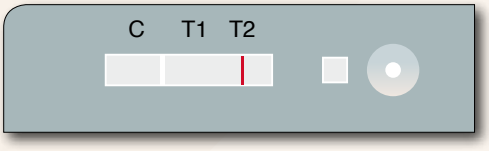


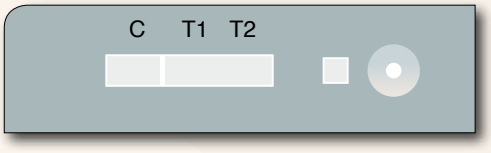
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection. Two lines 'C' and 'T1' appear in the results window.

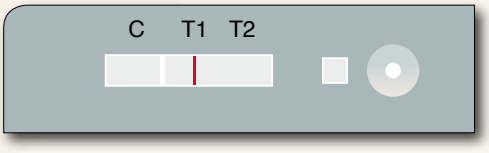


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.





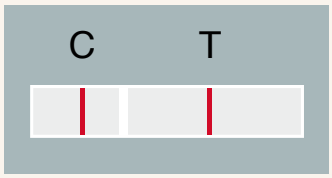




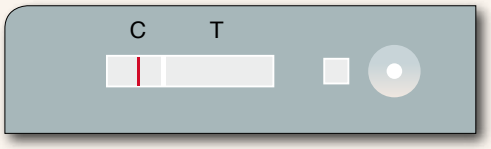
[1] vom, *P. vivax*, *P. ovale*, *P. malariae*

Type I: Guide to results of generic Pv malaria RDTs

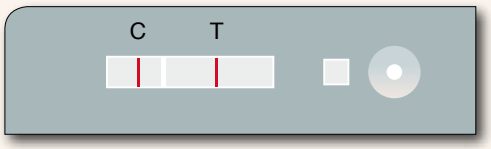
Results window: C=control line; T=test line with bound *P. vivax*-specific pLDH.



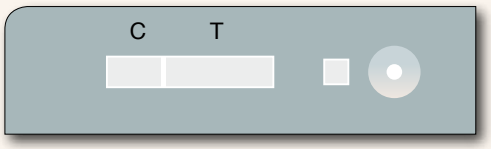
Negative results: Only one line 'C' appears in the results window.

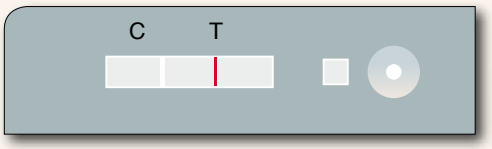


Positive results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



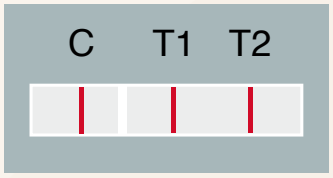
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



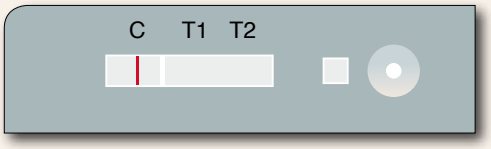


Type J: Guide to results of generic Pf-Pf malaria RDTs

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

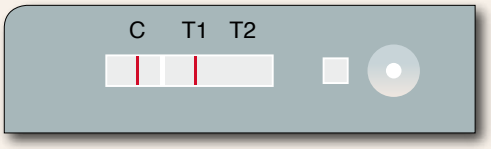


Negative results: Only one line 'C' appears in the results window.

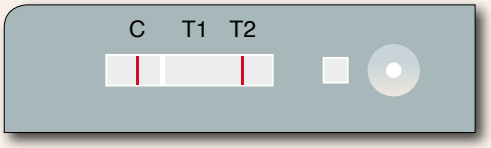


Positive results:

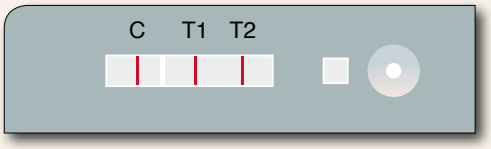
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



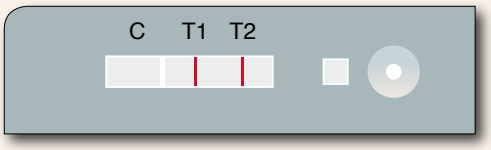
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.

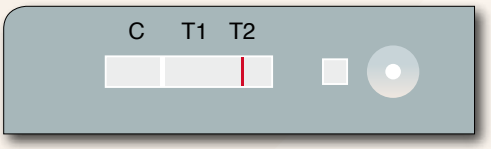


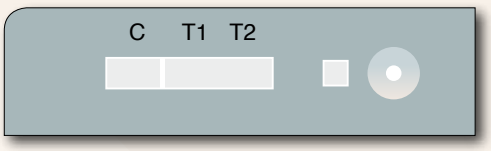
P. falciparum infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

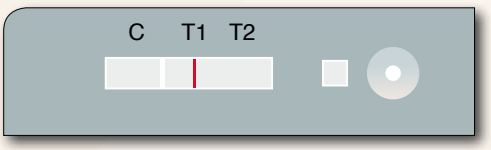


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



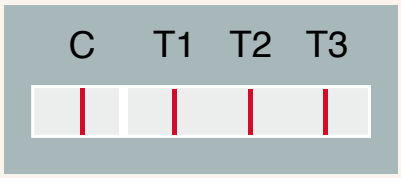




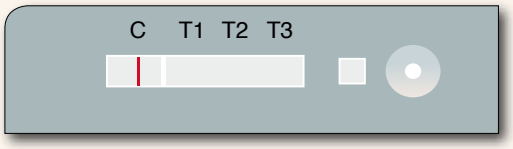


Type K: Guide to results of generic Pv-Pf-Pf malaria RDTs

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

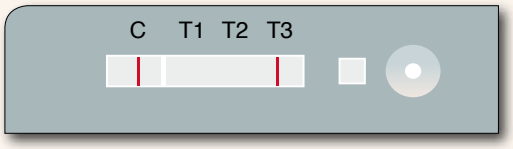


Negative results: Only one line 'C' appears in the results window.

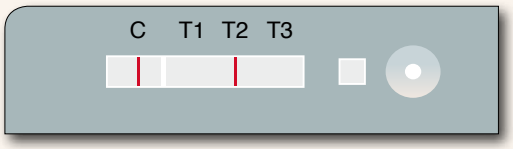


Positive results:

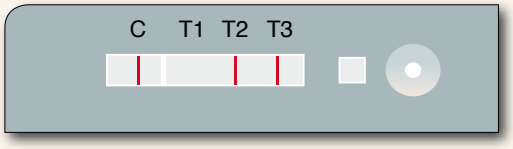
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



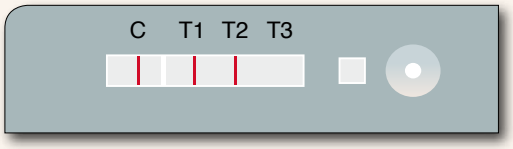
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



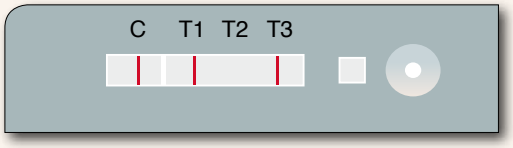
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



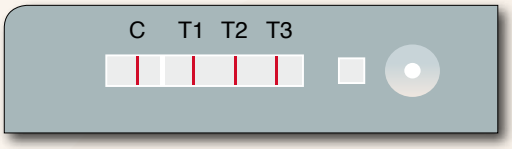
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



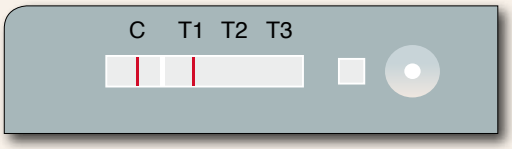
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T3' appear in the results window.



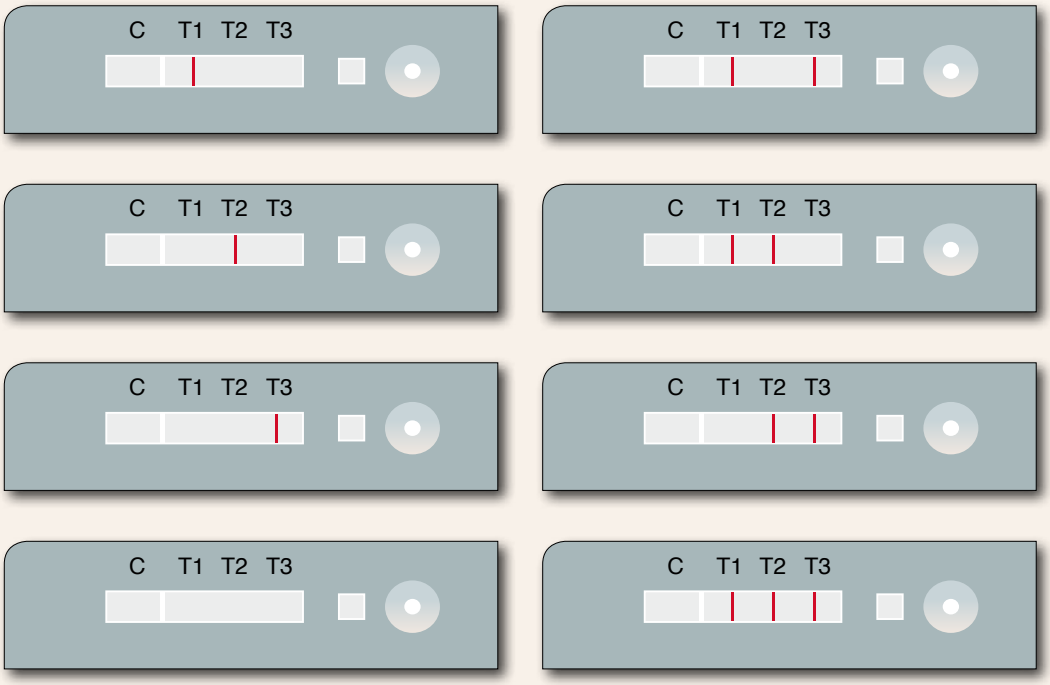
P. falciparum infection and *P. vivax* mixed infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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

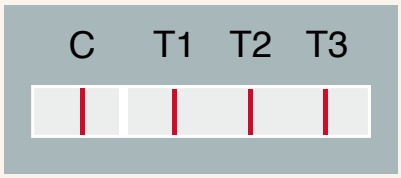


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

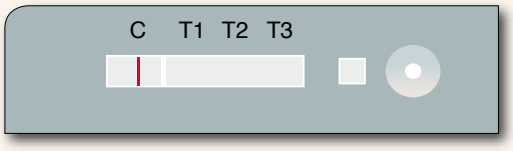


Type L: Guide to results of generic pan-Pf-Pf malaria RDTs

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

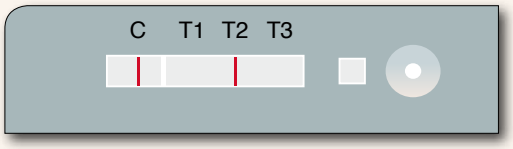


Negative results: Only one line 'C' appears in the results window.

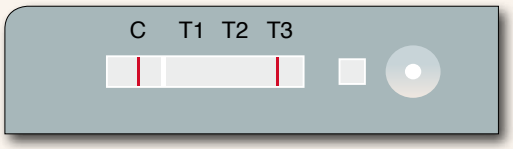


Positive results:

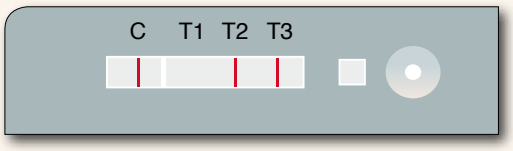
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



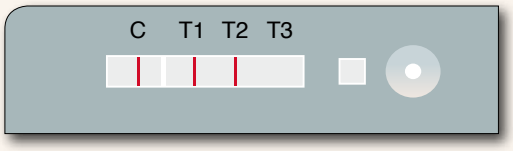
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



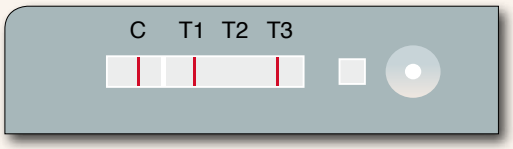
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



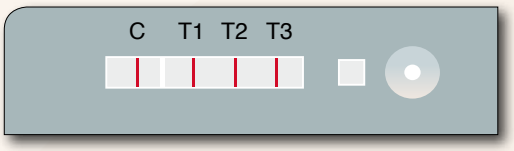
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T2' appear in the results window.



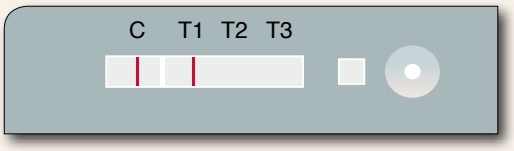
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



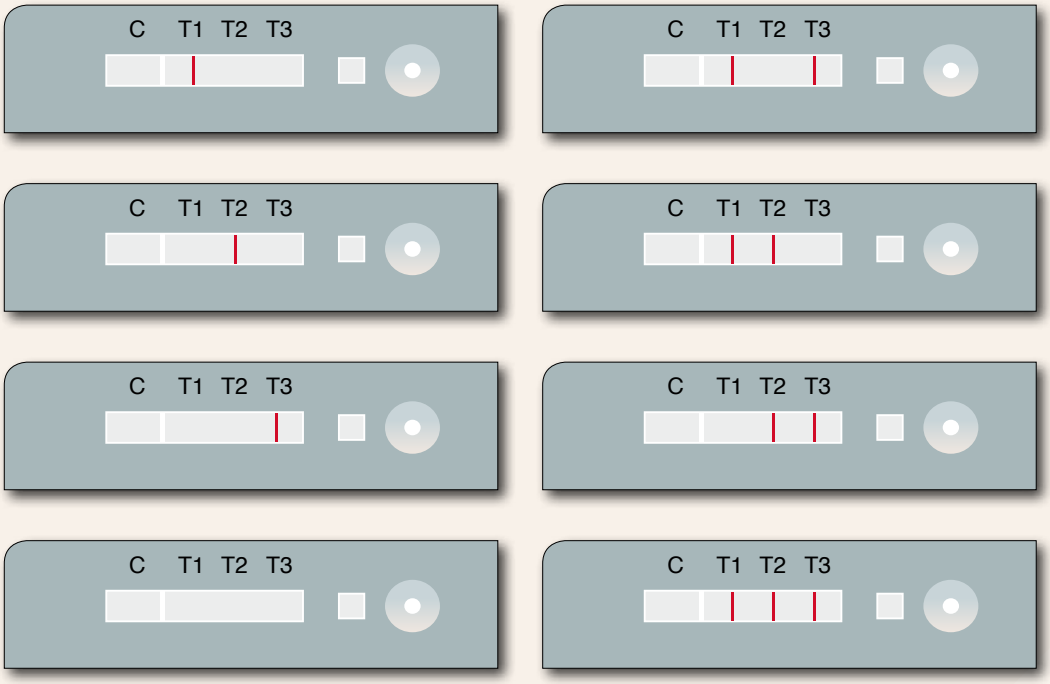
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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



Invalid results: No 'C' line appears in the results window. Repeat the test with 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 Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	19.0	19.0	19.0	20.0	19.0	19.0	20.0	20.0
Avantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	20.0	19.0	19.0	20.0	18.0	18.0	20.0	20.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	19.0	19.0	19.0	19.0	19.0	19.0	20.0	20.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	20.0	20.0	20.0	20.0	19.0	19.0	19.0 (19)	19.0 (19)
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Pf and pan										
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	20.0	17.0 (19)	17.0 (19)	20.0	18.0 (19)	18.0 (19)	20.0	20.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	20.0	20.0	20.0	20.0	19.0	19.0	19.0 (19)	20.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	12.0	9.0	7.0	7.0	4.0	0.0	20.0	20.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	20.0	18.0	18.0	20.0	20.0	20.0	20.0	20.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	20.0	19.0	19.0	19.0	20.0	19.0	20.0	20.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	19.0	20.0	19.0	20.0	19.0	19.0	20.0	20.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	20.0	19.0	19.0	20.0	19.0	19.0	20.0	20.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	20.0	19.0	19.0	18.0	19.0	18.0	20.0	20.0
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	20.0	19.0	19.0	20.0	20.0	20.0	19.0	20.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	17.0	16.0	15.0	15.0	13.0	12.0	20.0	20.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	20.0	19.0 (19)	19.0 (19)	19.0 (19)	19.0 (19)	18.0 (18)	20.0	20.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	12.0	13.0	7.0	15.0	7.0	4.0	20.0	20.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	20.0	20.0	20.0	19.0 (19)	20.0	19.0 (19)	20.0	20.0

Table A3.1 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=20) Total positive results returned							
			200 parasites/µL						2000 parasites/µL	
			Lot 1			Lot 2			Lot 1	Lot 2
			Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2	No. positive agreements[b] (max=20)	Test 1	Test 2
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	20.0	19.0	19.0	19.0	20.0	19.0	20.0	20.0
Pf and Pv/Pvom										
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	19.0	18.0 (19)	18.0 (19)	20.0	18.0 (19)	18.0 (19)	20.0	19.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	19.0	20.0	19.0	19.0	19.0	19.0	20.0	20.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
Pan only										
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	19.0	16.0	15.0	18.0	18.0	17.0	20.0	20.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] Results are based on the first reader's interpretation according to the manufacturer's 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 density (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 Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	3.8	57.5	33.8	5.0	0.0	0.0	2.5	27.5	42.5	27.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Avantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	3.8	17.5	60.0	16.3	2.5	0.0	0.0	5.0	25.0	70.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	0.0	7.5	41.3	42.5	8.8	0.0	0.0	2.5	5.0	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	0.0	5.0	33.8	45.0	16.3	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	0.0	6.3	33.8	43.8	16.3	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	5.0	28.8	57.5	8.8	0.0	0.0	0.0	15.0	65.0	20.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	1.3	12.5	45.0	30.0	11.3	0.0	0.0	2.5	7.5	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	0.0	3.8	22.5	63.8	10.0	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	0.0	10.0	46.3	35.0	8.8	0.0	0.0	2.5	7.5	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																						
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	6.3	15.0	58.8	16.3	3.8	0.0	0.0	7.5	32.5	60.0	52.5	42.5	5.0	0.0	0.0	5.0	40.0	55.0	0.0	0.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	1.3	26.3	43.8	25.0	3.8	2.5	0.0	7.5	22.5	67.5	58.8	41.3	0.0	0.0	0.0	2.5	32.5	57.5	7.5	0.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	60.0	40.0	0.0	0.0	0.0	0.0	25.0	75.0	0.0	0.0	95.0	5.0	0.0	0.0	0.0	0.0	72.5	27.5	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	2.5	32.5	57.5	7.5	0.0	0.0	0.0	5.0	32.5	62.5	10.0	87.5	2.5	0.0	0.0	0.0	0.0	52.5	47.5	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	1.3	7.5	38.8	47.5	5.0	0.0	0.0	2.5	7.5	90.0	35.0	53.8	11.3	0.0	0.0	0.0	12.5	70.0	17.5	0.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	23.8	51.3	25.0	0.0	0.0	0.0	5.0	17.5	77.5	65.0	35.0	0.0	0.0	0.0	0.0	62.5	37.5	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	0.0	8.8	42.5	37.5	11.3	0.0	0.0	2.5	5.0	92.5	12.5	85.0	2.5	0.0	0.0	0.0	0.0	67.5	32.5	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	0.0	6.3	30.0	51.3	12.5	0.0	0.0	0.0	5.0	95.0	38.8	57.5	1.3	0.0	2.5	0.0	45.0	47.5	2.5	5.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	1.3	7.5	61.3	26.3	3.8	0.0	0.0	0.0	20.0	80.0	32.5	65.0	2.5	0.0	0.0	0.0	10.0	87.5	2.5	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	2.5	26.3	56.3	11.3	3.8	0.0	0.0	5.0	27.5	67.5	82.5	17.5	0.0	0.0	0.0	0.0	60.0	40.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	2.5	27.5	46.3	16.3	7.5	0.0	0.0	2.5	12.5	85.0	77.5	20.0	2.5	0.0	0.0	0.0	60.0	40.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	2.5	11.3	46.3	32.5	7.5	0.0	0.0	2.5	20.0	77.5	76.3	23.8	0.0	0.0	0.0	2.5	55.0	40.0	2.5	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	5.0	15.0	51.3	23.8	5.0	0.0	0.0	2.5	5.0	92.5	97.5	1.3	1.3	0.0	0.0	52.5	35.0	12.5	0.0	0.0
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0	8.8	53.8	33.8	3.8	0.0	0.0	2.5	17.5	80.0	82.5	17.5	0.0	0.0	0.0	0.0	37.5	62.5	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	1.3	6.3	28.8	42.5	21.3	2.5	0.0	0.0	5.0	92.5	70.0	28.8	1.3	0.0	0.0	0.0	27.5	65.0	5.0	2.5
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	23.8	28.8	35.0	11.3	1.3	0.0	2.5	10.0	40.0	47.5	26.3	42.5	28.8	2.5	0.0	0.0	2.5	45.0	45.0	7.5
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	3.8	5.0	50.0	31.3	10.0	0.0	0.0	2.5	17.5	80.0	67.5	32.5	0.0	0.0	0.0	0.0	7.5	90.0	2.5	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	41.3	57.5	1.3	0.0	0.0	0.0	40.0	60.0	0.0	0.0	76.3	21.3	2.5	0.0	0.0	45.0	52.5	2.5	0.0	0.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	0.0	1.3	30.0	55.0	13.8	0.0	0.0	0.0	2.5	97.5	22.5	70.0	7.5	0.0	0.0	0.0	0.0	60.0	37.5	2.5
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	0.0	3.8	31.3	48.8	16.3	0.0	0.0	0.0	10.0	90.0	18.8	77.5	2.5	1.3	0.0	0.0	2.5	55.0	40.0	2.5
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	11.3	58.8	27.5	2.5	0.0	0.0	5.0	27.5	67.5	83.8	16.3	0.0	0.0	0.0	0.0	30.0	65.0	5.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	5.0	43.8	42.5	8.8	0.0	0.0	2.5	2.5	95.0	91.3	7.5	1.3	0.0	0.0	5.0	62.5	32.5	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	1.3	42.5	47.5	8.8	0.0	0.0	0.0	5.0	50.0	45.0	78.8	21.3	0.0	0.0	0.0	20.0	80.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	2.5	27.5	56.3	13.8	0.0	0.0	0.0	5.0	95.0	57.5	42.5	0.0	0.0	0.0	0.0	5.0	60.0	35.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	2.5	27.5	52.5	16.3	1.3	0.0	0.0	10.0	27.5	62.5	100.0	0.0	0.0	0.0	0.0	10.0	87.5	2.5	0.0	0.0

Table A3.2 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL				
			Percentage distribution of Pf test band intensity[b] (n=80)					Percentage distribution of Pf test band intensity[b] (n=40)					Percentage distribution of pan test band intensity[b] (n=80)					Percentage distribution of pan test band intensity[b] (n=40)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf and Pv/Pvom																						
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	13.8	50.0	28.8	7.5	0.0	0.0	5.0	15.0	80.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	6.3	3.8	43.8	40.0	6.3	2.5	0.0	2.5	0.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	1.3	16.3	66.3	15.0	1.3	0.0	0.0	0.0	60.0	40.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	1.3	1.3	40.0	48.8	8.8	0.0	0.0	2.5	5.0	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	3.8	42.5	47.5	6.3	0.0	0.0	0.0	10.0	45.0	45.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	1.3	8.8	42.5	41.3	6.3	0.0	0.0	2.5	10.0	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pan only																						
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	11.3	85.0	3.8	0.0	0.0	0.0	0.0	50.0	47.5	2.5
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.3	95.0	3.8	0.0	0.0	0.0	0.0	37.5	55.0	7.5

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] Denotes no band visible

[b] Calculations include invalid tests

Annex 4: Phase-2 results

Table A4.1: Lot variation 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=100) 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=100)	Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2
Pf only																		
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	70.0 (99)	63.0	59.0 (99)	85.0	83.0	73.0	93.0	99.0 (99)	NA	NA	NA	NA	NA	NA	NA	NA
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	92.0	95.0	92.0	94.0	94.0	93.0	99.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	96.0	94.0	93.0	96.0	98.0	95.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	93.0 (99)	96.0 (100)	91.0 (99)	95.0	94.0	93.0	99.0 (99)	99.0 (99)	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	97.0	99.0	97.0	97.0	96.0	95.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	82.0	81.0	75.0	89.0 (99)	86.0	84.0 (99)	93.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	90.0	84.0	83.0	97.0	92.0	91.0	89.0 (95)	95.0 (97)	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	96.0	96.0	96.0	99.0	98.0	97.0	100.0	99.0	NA	NA	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	92.0	93.0	89.0	95.0	92.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																		
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	79.0	77.0	72.0	80.0	79.0	75.0	97.0	94.0 (99)	23.0 (34)	27.0	17.0 (34)	29.0	24.0	23.0	35.0	34.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	91.0 (96)	87.0 (94)	81.0 (90)	96.0 (99)	98.0	95.0 (99)	97.0 (97)	100.0	28.0 (34)	23.0 (31)	21.0 (30)	34.0	31.0 (34)	31.0 (34)	34.0	35.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	48.0	50.0	42.0	43.0	44.0	35.0	96.0	95.0	35.0	35.0	35.0	35.0	33.0	33.0	34.0	35.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	91.0	92.0	87.0	90.0	91.0	87.0	100.0	100.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0	34.0 (34)
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	82.0	82.0	79.0	81.0	82.0	79.0	98.0 (98)	99.0	33.0	31.0	30.0	32.0	29.0	29.0	34.0	35.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	84.0	87.0	82.0	87.0	86.0	82.0	97.0	97.0	32.0	34.0	31.0	32.0	33.0	30.0	35.0	35.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	94.0	93.0	91.0	94.0	97.0	94.0	100.0	100.0	34.0	35.0	34.0	35.0	34.0	34.0	35.0	35.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	95.0	95.0	93.0	96.0	91.0	90.0	100.0	99.0	26.0	30.0	24.0	28.0	32.0	27.0	32.0	33.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	93.0	94.0	91.0	96.0	94.0	93.0	100.0	100.0	33.0	33.0	31.0	35.0	33.0	33.0	34.0(34)	32.0(33)
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	85.0	87.0	84.0	89.0	86.0	85.0	100.0	100.0	32.0 (34)	34.0	31.0 (34)	33.0	31.0	29.0	35.0	35.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	89.0	91.0	87.0	90.0	88.0	86.0	100.0	100.0	32.0	31.0	29.0	32.0	34.0	31.0	35.0	35.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	87.0	91.0	85.0	94.0	90.0	89.0	100.0	100.0	29.0	24.0	21.0	27.0	28.0	23.0	35.0	31.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	76.0	72.0	70.0	78.0	79.0	77.0	98.0	98.0	14.0	10.0	8.0	10.0	12.0	6.0	33.0	32.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	95.0 (99)	94.0	92.0 (99)	91.0 (98)	93.0 (99)	88.0 (97)	100.0	99.0 (99)	35.0	33.0 (34)	33.0 (34)	35.0	32.0 (34)	32.0 (34)	34.0	35.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	99.0	99.0	98.0	97.0	96.0	94.0	98.0	100.0	26.0	23.0	17.0	29.0	31.0	26.0	33.0	35.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	74.0 (99)	69.0	65.0 (99)	68.0	66.0 (99)	64.0 (99)	98.0	94.0 (99)	8.0	7.0	4.0	2.0	3.0	2.0	35.0	34.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	92.0	91.0 (98)	88.0 (98)	97.0	96.0	95.0	100.0	99.0 (99)	34.0 (34)	33.0 (34)	32.0 (33)	35.0	33.0	33.0	34.0 (34)	35.0

Table A4.1 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=100) 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=100)	Test 1	Test 2	No. positive agreements[c] (max=100)	Test 1	Test 2	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2	No. positive agreements[c] (max=35)	Test 1	Test 2
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	76.0	75.0	65.0	68.0	70.0	54.0	99.0	98.0	14.0	18.0	9.0	23.0	15.0	11.0	23.0	22.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	98.0	99.0	97.0	99.0	96.0	96.0	100.0	100.0	16.0	19.0	14.0	25.0	26.0	19.0	19.0	23.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	94.0	95.0	93.0	97.0	94.0 (99)	93.0 (99)	100.0	100.0	33.0	35.0	33.0	31.0	25.0	23.0	34.0	33.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	90.0	88.0 (99)	88.0 (99)	92.0	91.0	88.0	100.0	100.0	34.0	35.0	34.0	33.0	34.0	32.0	35.0	34.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	95.0	95.0	94.0	96.0	98.0	96.0	99.0 (99)	100.0	24.0	24.0	19.0	28.0	24.0	22.0	34.0	35.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	84.0	78.0	76.0	93.0	88.0	87.0	94.0	100.0	24.0	21.0	17.0	25.0	25.0	21.0	31.0	35.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/ 05FK63	Standard Diagnostics Inc.	97.0	96.0	95.0	98.0	96.0	95.0	100.0	99.0	33.0	34.0	32.0	35.0	34.0	34.0	35.0	34.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	89.0	89.0	86.0	91.0	88.0	87.0	97.0 (99)	99.0	8.0 (34)	10.0	5.0 (34)	6.0	6.0	3.0	33.0 (34)	34.0
Pf and Pv/Pvom																		
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	91.0	89.0	86.0	87.0	86.0	84.0	100.0	99.0	29.0	28.0	24.0	23.0	22.0	17.0	35.0	35.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	89.0 (94)	92.0	85.0 (94)	92.0 (99)	94.0 (98)	90.0 (97)	93.0 (96)	99.0 (99)	32.0	34.0	31.0	30.0 (33)	33.0	28.0 (33)	34.0	34.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (P) Ltd.	91.0 (99)	94.0	86.0 (99)	95.0	98.0	94.0	99.0 (99)	100.0	27.0 (34)	29.0	25.0 (34)	30.0	33.0	29.0	34.0 (34)	35.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	98.0	95.0	95.0	98.0	97.0	96.0	100.0	100.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	70.0 (99)	73.0	63.0 (99)	83.0	81.0	80.0	91.0	100.0	23.0	23.0	20.0	24.0	26.0	20.0	30.0	35.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	94.0	90.0	89.0	94.0	94.0 (99)	90.0 (99)	100.0	98.0	28.0	16.0	14.0	26.0	21.0	17.0	35.0	34.0
Pan only																		
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	88.0	82.0	82.0	87.0	80.0	78.0	98.0	98.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	91.0	91.0	85.0	96.0	93.0	92.0	99.0	99.0	35.0	35.0	35.0	35.0	31.0	31.0	35.0	34.0

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] Results are based on the first reader's interpretation according to the manufacturer's instructions.

[b] 4 (4%) of the 100 *P. falciparum* dilution samples sets had 200 and 5000 parasites/µL and 2 (6%) of the 35 *P. vivax* dilution sample sets had 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 density (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 Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	24.5	46.8	24.8	3.8	0.3	4.0	13.0	29.0	31.0	23.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	6.3	27.3	42.3	18.3	6.0	0.5	2.5	11.0	17.0	69.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	4.0	18.0	32.5	31.3	14.3	0.0	1.0	4.0	19.0	76.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	5.3	14.8	26.0	28.0	26.0	1.0	0.0	2.0	10.0	87.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	2.8	13.5	28.5	33.3	22.0	0.0	0.5	2.0	15.0	82.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	15.5	33.0	37.5	13.3	0.8	3.5	4.5	17.5	37.0	37.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	9.3	22.3	33.5	22.3	12.8	4.0	0.5	7.5	14.0	74.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	2.8	10.5	26.3	36.8	23.8	0.5	0.0	3.5	12.0	84.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	7.0	19.0	35.5	28.8	9.8	0.0	0.5	6.5	18.5	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																																
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	21.3	34.8	34.0	10.0	0.0	4.5	5.5	22.0	36.0	32.0	81.0	15.5	3.5	0.0	0.0	21.5	46.0	31.0	1.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	7.0	34.3	42.3	14.3	2.3	1.5	2.5	11.5	33.5	51.0	70.0	29.5	0.5	0.0	0.0	9.0	42.5	44.5	4.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	53.8	44.8	1.5	0.0	0.0	4.5	26.5	50.0	18.5	0.5	69.3	30.8	0.0	0.0	0.0	5.5	42.5	47.5	4.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	9.0	32.3	43.0	13.3	2.5	0.0	1.5	14.0	20.5	64.0	12.3	62.8	25.0	0.0	0.0	2.0	2.0	42.5	43.5	10.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	18.3	12.8	31.5	29.0	8.5	1.5	2.0	9.5	23.5	63.5	78.5	20.5	1.0	0.0	0.0	15.0	21.0	51.0	12.0	1.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	14.0	24.5	40.5	19.3	1.8	3.0	2.0	13.0	24.0	58.0	78.0	21.8	0.3	0.0	0.0	9.5	41.0	49.0	0.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	5.5	14.0	31.5	23.5	25.5	0.0	0.5	2.0	12.0	85.5	21.0	66.3	12.8	0.0	0.0	1.0	8.5	49.0	33.0	8.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	5.8	20.3	39.3	27.3	7.5	0.5	2.5	7.5	17.0	72.5	65.5	32.8	1.3	0.3	0.3	5.0	50.0	45.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	5.8	22.0	44.8	25.3	2.3	0.0	0.5	11.5	24.5	63.5	62.5	37.0	0.5	0.0	0.0	4.5	24.5	57.0	14.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	13.3	21.3	39.3	22.8	3.5	0.0	2.0	13.0	19.0	66.0	74.5	25.3	0.3	0.0	0.0	7.0	33.5	51.0	8.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	10.5	21.0	34.8	24.3	9.5	0.0	1.0	7.0	14.0	78.0	69.0	29.8	1.3	0.0	0.0	3.0	36.0	53.0	7.5	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	9.5	26.8	37.3	22.5	4.0	0.0	2.0	12.0	26.0	60.0	86.5	12.0	1.5	0.0	0.0	15.5	43.5	39.0	2.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	23.8	21.8	26.0	19.8	8.8	2.0	4.0	10.5	11.5	72.0	92.3	6.8	1.0	0.0	0.0	43.0	28.5	28.0	0.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	6.8	17.3	38.8	30.8	6.5	0.5	0.5	4.5	23.5	71.0	62.5	36.5	0.8	0.3	0.0	3.0	29.5	56.5	10.5	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	2.3	17.8	35.3	28.3	16.5	1.0	0.5	6.5	16.0	76.0	62.5	30.5	5.8	1.3	0.0	4.5	23.5	48.0	23.5	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	30.8	38.3	26.0	4.8	0.3	4.0	12.5	20.0	34.5	29.0	40.8	46.5	12.5	0.3	0.0	8.5	18.5	39.5	31.5	2.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	5.8	18.3	43.8	27.5	4.8	0.5	0.0	10.0	25.5	64.0	62.0	37.3	0.8	0.0	0.0	2.5	28.0	58.5	11.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	27.8	69.3	3.0	0.0	0.0	1.5	26.5	48.5	21.0	2.5	7.8	91.0	1.3	0.0	0.0	6.0	89.5	4.0	0.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.2 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µL Percentage distribution of Pf test band intensity[c] (n=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
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	2.0	16.3	36.0	34.3	11.5	0.0	0.0	6.0	23.5	70.5	28.3	56.8	14.3	0.8	0.0	2.5	7.5	50.0	37.0	3.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	5.0	21.8	35.5	29.3	8.5	0.0	0.0	7.0	29.0	64.0	38.0	50.3	10.5	1.3	0.0	2.5	15.5	46.5	32.0	3.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	9.8	22.8	39.8	24.8	3.0	0.0	2.5	9.5	26.5	61.5	68.3	31.0	0.5	0.3	0.0	4.0	31.0	52.5	12.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	4.0	18.5	34.0	26.8	16.8	0.5	0.0	6.0	9.0	84.5	67.3	32.5	0.3	0.0	0.0	6.5	36.0	45.0	12.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	14.3	26.5	48.0	10.5	0.8	3.0	2.5	17.5	41.5	35.5	84.8	14.8	0.0	0.5	0.0	24.5	66.5	9.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	3.3	12.8	28.3	35.5	20.3	0.5	0.5	5.0	13.5	80.5	36.0	53.3	10.5	0.3	0.0	2.0	9.0	46.5	33.5	9.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	10.8	23.5	47.3	17.8	0.8	2.0	3.0	12.0	32.5	50.5	82.8	15.0	2.3	0.0	0.0	11.0	52.0	34.0	3.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv/Pvom																																
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	11.8	28.3	37.0	20.8	2.3	0.5	3.0	12.0	26.0	58.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	83.5	15.5	1.0	0.0	0.0	14.5	47.0	34.5	4.0	0.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	8.3	20.3	38.8	25.8	7.0	4.0	1.0	9.0	20.5	65.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.5	1.3	0.3	0.0	0.0	96.5	3.0	0.5	0.0	0.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	5.5	22.0	46.5	22.0	4.0	0.0	0.0	13.5	42.0	44.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	72.8	25.8	1.5	0.0	0.0	13.0	58.5	28.0	0.5	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	3.0	17.5	41.3	27.8	10.5	0.0	0.0	8.0	20.0	72.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	78.5	19.0	2.5	0.0	0.0	91.0	8.0	1.0	0.0	0.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	23.3	26.8	38.0	11.0	1.0	4.5	5.0	21.5	26.5	42.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.0	1.3	0.3	0.0	0.5	99.5	0.0	0.0	0.5	0.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	7.0	15.0	35.5	27.8	14.8	1.0	0.5	7.0	12.0	79.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.5	1.5	0.0	0.0	0.0	98.5	1.0	0.0	0.0	0.5
Pan only																																
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	15.8	61.8	22.5	0.0	0.0	2.0	1.5	43.5	44.0	9.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.3	64.3	28.0	0.5	0.0	1.0	2.0	25.0	43.5	28.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] Denotes no visible band

[b] 4 (4%) of the 100 *P. falciparum* dilution samples sets had 200 and 5000 parasites/µL and 2 (6%) of the 35 *P. vivax* dilution sample sets had 200 and 5000 parasites/µL

[c] Calculations include invalid tests

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 density (parasites/µL)

Product	Catalogue number	Manufacturer	200 parasites/µL					2000[b] parasites/µL					200 parasites/µL					2000[b] parasites/µL				
			Percentage distribution of pan test band intensity[c] (n=140)					Percentage distribution of pan test band intensity[c] (n=70)					Percentage distribution of Pv test band intensity[c] (n=140)					Percentage distribution of Pv test band intensity[c] (n=70)				
			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 Pf Test	ITP11002TC1/ TC40	InTec Products, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Avantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																						
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	26.4	65.7	7.9	0.0	0.0	1.4	1.4	57.1	37.1	2.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	10.7	79.3	10.0	0.0	0.0	0.0	2.9	51.4	32.9	12.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.7	77.9	20.0	1.4	0.0	1.4	0.0	11.4	67.1	20.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	8.6	80.0	10.7	0.7	0.0	0.0	0.0	17.1	82.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	10.0	56.4	32.1	1.4	0.0	1.4	0.0	7.1	44.3	47.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	6.4	77.1	16.4	0.0	0.0	0.0	0.0	38.6	50.0	11.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	0.7	11.4	72.1	15.0	0.7	0.0	0.0	0.0	12.9	87.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	5.0	76.4	18.6	0.0	0.0	0.0	0.0	24.3	51.4	24.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	1.4	67.1	27.9	3.6	0.0	4.3	0.0	17.1	55.7	22.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	6.4	84.3	8.6	0.7	0.0	0.0	0.0	21.4	60.0	18.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	7.9	62.9	27.9	1.4	0.0	0.0	1.4	11.4	52.9	34.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	22.9	70.0	7.1	0.0	0.0	1.4	1.4	55.7	38.6	2.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	54.3	37.9	7.9	0.0	0.0	0.0	2.9	31.4	42.9	22.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	Humasis Co., Ltd.	3.6	64.3	30.0	2.1	0.0	1.4	0.0	17.1	55.7	25.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	18.6	58.6	21.4	1.4	0.0	0.0	0.0	18.6	61.4	20.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	82.9	17.1	0.0	0.0	0.0	1.4	52.9	40.0	5.7	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	2.1	57.9	38.6	1.4	0.0	1.4	0.0	11.4	68.6	18.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	2.1	80.0	17.1	0.7	0.0	0.0	0.0	27.1	45.7	27.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	0.0	44.3	51.4	4.3	0.0	0.0	0.0	7.1	55.7	37.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	2.1	54.3	37.9	5.7	0.0	0.0	0.0	12.9	45.7	41.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	2.9	72.9	24.3	0.0	0.0	0.0	0.0	15.7	60.0	24.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	27.9	62.1	10.0	0.0	0.0	0.0	2.9	50.0	35.7	11.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	30.7	69.3	0.0	0.0	0.0	2.9	10.0	80.0	7.1	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.3 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µL					2000[b] parasites/µL					200 parasites/µL					2000[b] parasites/µL				
			Percentage distribution of pan test band intensity[c] (n=140)					Percentage distribution of pan test band intensity[c] (n=70)					Percentage distribution of Pv test band intensity[c] (n=140)					Percentage distribution of Pv test band intensity[c] (n=70)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	2.1	25.7	59.3	12.9	0.0	0.0	0.0	8.6	24.3	67.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	77.9	19.3	2.9	0.0	0.0	4.3	30.0	58.6	7.1	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv/Pvom																						
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	27.1	64.3	8.6	0.0	0.0	0.0	1.4	40.0	55.7	2.9
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.9	82.1	10.0	0.0	0.0	2.9	1.4	50.0	41.4	4.3
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/ PAN-50	Bhat Bio-Tech India (P) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	15.0	76.4	8.6	0.0	0.0	1.4	0.0	45.7	41.4	11.4
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	27.9	70.7	1.4	0.0	0.0	0.0	2.9	55.7	41.4
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	31.4	57.9	10.7	0.0	0.0	7.1	1.4	35.7	51.4	4.3
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	35.0	60.7	4.3	0.0	0.0	1.4	2.9	55.7	32.9	7.1
Pan only																						
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	0.0	15.0	72.9	10.7	1.4	0.0	0.0	2.9	32.9	64.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	2.9	0.7	67.1	25.0	4.3	1.4	0.0	0.0	2.9	95.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] Denotes no visible band

[b] 2 (6%) of the 35 *P. vivax* dilution sample sets had 200 and 5000 parasites/µL

[c] Pan test line

[d] *P. vivax* test line

[e] Calculations include invalid tests

Table A4.4: Panel detection score of phase-2 wild-type *P. falciparum* at low (200) and high (2000) parasite density (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=58)	Asia (n=23)	South America (n=19)	Africa (n=58)	Asia (n=23)	South America (n=19)
Pf only								
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	43.1	65.2	68.4	91.4	91.3	100.0
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	82.8	100.0	94.7	100.0	95.7	100.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	84.5	100.0	100.0	100.0	100.0	100.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	86.2	95.7	84.2	100.0	100.0	100.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	91.4	100.0	100.0	100.0	100.0	100.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	62.1	87.0	84.2	91.4	91.3	100.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	70.7	91.3	89.5	89.5	90.9	100.0
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	91.4	100.0	100.0	98.3	100	100.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	75.9	95.7	94.7	100	100	100.0
Pf and pan								
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	56.9	73.9	84.2	89.7	95.7	94.7
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	81.0	100.0	94.7	100.0	100.0	100.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	37.9	26.1	10.5	93.1	100.0	89.5
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	75.9	100.0	89.5	100.0	100.0	100.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	63.8	100.0	89.5	100.0	95.7	100.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	67.2	87.0	94.7	94.8	95.7	89.5
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	82.8	100.0	100.0	100.0	100.0	100.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	82.8	100.0	94.7	100.0	95.7	100.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	82.8	100.0	100.0	100.0	100.0	100.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	74.1	100.0	89.5	100.0	100.0	100.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	74.1	100.0	100.0	100.0	100.0	100.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	75.9	95.7	94.7	100.0	100.0	100.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	53.4	82.6	89.5	94.8	100.0	94.7
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	82.8	100.0	100.0	100.0	100.0	100.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	87.9	100.0	100.0	96.6	100.0	100.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	50.0	73.9	78.9	91.4	100.0	100.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	81.0	100.0	100.0	100.0	100.0	100.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	48.3	34.8	26.3	98.3	95.7	94.7
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	91.4	100.0	100.0	100.0	100.0	100.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	84.5	95.7	100.0	100.0	100.0	100.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	75.9	100.0	100.0	100.0	100.0	100.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	86.2	100.0	100.0	100.0	100.0	100.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	65.5	87.0	84.2	93.1	91.3	100.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	91.4	95.7	100.0	98.3	100.0	100.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	75.9	100.0	100.0	94.8	100.0	100.0

Table A4.4 *(continued)*

Product	Catalogue number	Manufacturer	200 parasites/µL Panel detection score[a] by continent of sample origin			2000[b] parasites/µL Panel detection score[a] by continent of sample origin		
			Africa (n=58)	Asia (n=23)	South America (n=19)	Africa (n=58)	Asia (n=23)	South America (n=19)
Pf and Pv/Pvom								
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	70.7	95.7	94.7	100.0	95.7	100.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	79.3	91.3	94.7	96.6	95.7	100.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	75.9	95.7	94.7	100.0	100.0	100.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	87.9	95.7	100.0	100.0	100.0	100.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	46.6	82.6	89.5	89.7	91.3	94.7
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	79.3	100.0	94.7	96.6	100.0	100.0
Pan only								
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	74.1	87.0	73.7	98.3	100.0	94.7
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	74.1	95.7	100.0	98.3	100.0	100.0

Africa: Central African Republic, Ethiopia, Kenya, Madagascar, Nigeria, United Republic of Tanzania
Asia: Cambodia, Myanmar, the Philippines
South America: Colombia, Peru
Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*
[a] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive
[b] 4 (4%) of the 100 *P. falciparum* dilution samples sets had 200 and 5000 parasites/µL

Table A4.5: Phase-2 *P. falciparum* test line false-positive rates for wild-type *P. vivax* samples at low (200) and high (2000) parasite density (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 Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	7.1	0.0	3.6	11.4	0.0	5.7
Avantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	2.9	1.4	2.1	2.9	0.0	1.4
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	0.0	1.4	0.7	0.0	0.0	0.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	7.1	0.0	3.6	8.6	0.0	4.3
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	5.7	17.1	11.4	11.4	14.3	12.9
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	0.0	0.0	0.0	2.9	2.9	2.9
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	1.4	2.9	2.1	2.9	0.0	1.4
Pf and pan								
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	0.0 (69)	0.0	0.0 (139)	0.0	0.0	0.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	10.8 (65)	2.9 (69)	6.7 (134)	2.9	0.0	1.4
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0 (34)	0.0 (69)
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	0.0	1.4	0.7	0.0	0.0	0.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	1.4	0.0	0.7	0.0	0.0	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	17.1	7.1	12.1	8.6	5.7	7.1
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	4.3	1.4	2.9	0.0 (34)	3. (33)	1.5 (67)
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0 (69)	1.4	0.7 (139)	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	5.7	21.4	13.6	5.7	8.6	7.1
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0 (69)	0.0 (69)	0.0 (138)	2.9	0.0	1.4
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	8.6	0.0	4.3	5.7	0.0	2.9
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	4.3	4.3	4.3	0.0	0.0	0.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0 (68)	1.4	0.7 (138)	0.0 (34)	0.0	0.0 (69)
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	54.3	41.4	47.9	34.3	37.1	35.7
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	50.0	27.1	38.6	45.7	34.3	40.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	2.9	15.7	9.3	2.9	5.7	4.3
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	0.0	0.0	2.9	1.4
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	1.4	0.0	0.7	2.9	0.0	1.4
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	5.7	0.0	2.9	11.4	0.0	5.7
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	1.4	0.0	0.7	0.0	2.9	1.4
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	0.0 (69)	1.4	0.7 (139)	0.0 (34)	0.0	0.0 (69)

Table A4.5 *(continued)*

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 and Pv/Pvom								
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	2.9	10.3 (68)	6.5 (138)	0.0	5.7	2.9
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	10.1 (69)	1.4	5.8 (139)	5.9 (34)	2.9	4.3 (69)
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	51.4	55.7	53.6	42.9	25.7	34.3
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	10.0	1.4	5.7	5.7	0.0	2.9
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	1.4	4.3	2.9	0.0	5.7	2.9
Pan only								
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	NA	NA	NA	NA	NA	NA

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

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

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

Table A4.6: Phase-2 pan (or *P. vivax*/\Pvom) test line false-positive rate for non-*P. falciparum* infection on phase-2 wild-type *P. falciparum* samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=100)					
			200 parasites/µL False-positive non-Pf infection (%)			2000[a] parasites/µL False-positive non-Pf infection (%)		
			Lot 1 (n=200)	Lot 2 (n=200)	Overall (n=400)	Lot 1 (n=100)	Lot 2 (n=100)	Overall (n=200)
Pf only								
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	NA	NA	NA	NA	NA	NA
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	NA	NA	NA	NA	NA	NA
Pf and pan								
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	0.0	0.5	0.3	0.0	0.0 (99)	0.0 (199)
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0 (190)	0.5 (199)	0.3 (389)	0.0 (97)	0.0	0.0 (197)
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	1.5	1.5	1.5	1.0	0.0	0.5
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	3.0	4.0	3.5	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	0.5	1.0	0.8	0.0 (98)	1.0	0.5 (198)
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	1.0	0.5	3.0	1.0	2.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	0.5	2.5	1.5	0.0	0.0	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	0.0	0.5	0.3	0.0	1.0	0.5
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	0.5	0.0	0.3	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.5	0.3	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.5	0.3	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0	1.0 (197)	0.5 (396)	0.0	0.0 (99)	0.0 (199)
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	0.5	0.0	0.3	1.0	0.0	0.5
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	0.0	0.0 (199)	0.0 (398)	0.0	0.0 (99)	0.0 (199)
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0 (398)	0.0	0.0 (99)	0.0 (199)
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	23.0	22.0	22.5	1.0	2.0	1.5
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	1.0	0.0 (199)	0.5 (399)	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	0.0 (399)	0.0	0.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.5	0.5	0.5	0.0 (99)	0.0	0.0 (199)
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	3.5	0.5	2.0	1.0	0.0	0.5
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.5	1.0	0.8	0.0	1.0	0.5
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	0.0	0.0	0.0	1.0 (99)	0.0	0.5 (199)

Table A4.6 *(continued)*

Product	Catalogue number	Manufacturer	*P. falciparum* samples (n=100)					
			200 parasites/µL False-positive non-Pf infection (%)			2000[a] parasites/µL False-positive non-Pf infection (%)		
			Lot 1 (n=200)	Lot 2 (n=200)	Overall (n=400)	Lot 1 (n=100)	Lot 2 (n=100)	Overall (n=200)
Pf and Pv/Pvom								
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	18.5	14.5	16.5	91.0	80.0	85.5
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	1.5	1.5 (197)	1.5 (391)	3.1 (96)	4.0 (99)	3.6 (195)
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	23.6	31.0	27.3 (399)	86.9 (99)	88.0	87.4 (199)
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	20.5	22.5	21.5	10.0	8.0	9.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	3.5	0.5	2.0 (399)	1.0	0.0	0.5
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.5	2.5 (199)	1.5 (399)	0.0	3.0	1.5
Pan only								
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	NA	NA	NA	NA	NA	NA

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] 4 (4%) of the 100 *P. falciparum* dilution samples sets had 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=118)	Lot 2 (n=118)	Overall (n=236)	Lot 1 (n=26)	Lot 2 (n=26)	Overall (n=52)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	13.9 (115)	1.7	7.7 (233)	0.0	0.0	0.0	3.5	1.7	2.6
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	6.9	5.2	6.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	0.0	1.7	0.8	0.0	0.0	0.0	3.4	3.4	3.4
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	0.8	0.9 (117)	0.9 (235)	3.8	0.0	1.9	0.0	0.0	0.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	0.0	0.8	0.4	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK® MALARIA falciparum	0502_K25	BIOSYNEX	10.3	0.0	5.1	0.0	0.0	0.0	13.8	13.8	13.8
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	11.1 (117)	10.2	10.6 (235)	0.0	23.1	11.5	8.6	17.2	12.9
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.9
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	10.2	0.0	5.1	19.2	7.7	13.5	10.3	0.0	5.2
Pf and pan											
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	12.0 (117)	2.6 (117)	7.3 (234)	23.1	11.5	17.3	12.1	12.3 (57)	12.2 (115)
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	11.5 (113)	5.9	8.7 (231)	0.0	0.0	0.0	0.0	1.7	0.9
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.9	0.4	0.0	0.0	0.0	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0 (25)	0.0 (51)	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	5.2	5.2
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.8	0.0	0.4	0.0	0.0	0.0	0.0	3.4	1.7
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	0.0	0.8	0.4	3.8	0.0	1.9	5.2	1.7	3.4
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	7.6	15.3	11.4	7.7	26.9	17.3	34.5	25.9	30.2
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	2.5	0.8	1.7	3.8	0.0	1.9	12.1	8.6	10.3
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.8	1.7 (117)	1.3 (235)	0.0	11.5	5.8	3.6 (56)	3.4	3.5 (114)
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0 (117)	0.0	0.0 (235)	0.0	0.0	0.0	7.0 (57)	6.9	7.0 (115)
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	3.4	15.3	9.3	12.0 (25)	34.6	23.5 (51)	6.9	19.0	12.9
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.9 (117)	0.8	0.9 (235)	0.0	0.0 (25)	0.0 (51)	10.3	10.3	10.3
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	3.4	0.8	2.1	7.7	0.0	3.8	12.1	10.3	11.2
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	1.7	0.0	0.8	0.0	0.0	0.0	29.3	20.7	25.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.9 (116)	0.0 (116)	0.4 (232)	0.0 (25)	0.0	0.0 (51)	3.4	5.3 (57)	4.3 (115)
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	37.6 (117)	35.6	36.6 (235)	73.1	65.4	69.2	81.0	79.3	80.2
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	39.8	37.3	38.6	42.3	11.5	26.9	48.3	53.4	50.9
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	5.1	20.3	12.7	3.8	23.1	13.5	8.6	36.2	22.4
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.8	1.7	1.3	0.0	0.0	0.0	0.0	5.2	2.6
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	3.4	4.2	3.8	0.0	3.8	1.9	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	10.2	0.8	5.5	0.0	0.0	0.0	3.4	0.0	1.7
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	3.4	3.4	3.4
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	0.9 (117)	0.8	0.9 (235)	0.0	0.0	0.0	3.4	3.4	3.4

Table A4.7 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive Pf test lines on "clean[a]" negative samples			Percentage of false-positive Pf test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive Pf test lines on samples containing immunological factors[c]		
			Lot 1 (n=118)	Lot 2 (n=118)	Overall (n=236)	Lot 1 (n=26)	Lot 2 (n=26)	Overall (n=52)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf and Pv/Pvom											
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0 (117)	0.8	0.4 (235)	0.0 (25)	0.0	0.0 (51)	5.2	6.9	6.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	0.9 (115)	0.0 (117)	0.4 (232)	0.0 (23)	0.0 (23)	0.0 (46)	5.4 (56)	5.4 (56)	5.4 (112)
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	3.5 (114)	1.7	2.6 (232)	0.0 (25)	7.7	3.9 (51)	20.7	19.0	19.8
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	73.7	76.3	75.0	46.2	42.3	44.2	56.9	67.2	62.1
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	9.3	0.0	4.7	0.0	0.0	0.0	29.3	27.6	28.4
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	2.5	1.3	0.0	0.0	0.0	0.0	0.0	0.0
Pan only											
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0	6.9	8.6	7.8

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* spp. Pvom, *Plasmodium vivax, ovale* and *malariae*

[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

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-positives for *Plasmodium* spp. by infectious pathogen					
			Dengue		Leishmaniasis		Chagas	
			Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Pf only								
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	8.3	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	0.0	0.0	0.0	0.0	0.0	0.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	0.0	25.0	0.0	20.0	0.0	25.0
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	50.0	20.0	0.0	0.0
Pf and pan								
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	0.0	0.0	60.0	30.0	0.0	0.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0 (9)	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	16.7	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	8.3	0.0	0.0	0.0	0.0	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	0.0	8.3	20.0	40.0	0.0	50.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	8.3	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	8.3	0.0	10.0	0.0	25.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	9.1 (11)	41.7	0.0	40.0	50.0	50.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0	0.0	0.0	0.0 (9)	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	0.0	0.0	20.0	0.0	0.0	0.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0 (9)	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	100.0	100.0	100.0	100.0	100.0	100.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	58.3	25.0	30.0	0.0	25.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	8.3	33.3	0.0	0.0	0.0	50.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	8.3	0.0	0.0	0.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	8.3	10.0	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	8.3	25.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv/Pvom								

Table A4.8 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positives for *Plasmodium* spp. by infectious pathogen					
			Dengue		Leishmaniasis		Chagas	
			Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	0.0	0.0 (9)	0.0	0.0	0.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	0.0	0.0 (10)	0.0 (7)	0.0 (9)	0.0	0.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	8.3	8.3	0.0 (9)	10.0	0.0	25.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	75.0	58.3	20.0	10.0	50.0	100.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Pan only								
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* spp. Pvom, *Plasmodium vivax, ovale* and *malariae*

Table A4.9: Phase-2 false-positives 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	
			Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=26)	Lot 2 (n=26)	Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=14)	Lot 2 (n=14)
Pf only										
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	0.0	0.0	7.7	0.0	0.0	16.7	0.0	0.0
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	16.7	8.3	0.0	0.0	33.3	33.3	0.0	0.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	25.0	33.3	3.9	0.0	66.7	66.7	0.0	0.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	0.0	16.7	7.7	11.5	50.0	50.0	0.0	14.3
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	16.7	0.0	0.0
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	25.0	0.0	0.0	0.0	33.3	0.0	7.1	0.0
Pf and pan										
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	58.3	58.3	3.9	3.9	66.7	40.0 (5)	0.0	14.3
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0	0.0	0.0	3.9	33.3	16.7	0.0	0.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	25.0	16.7	0.0	3.9	33.3	50.0	0.0	0.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	66.7	50.0	0.0	3.9	16.7	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	16.7	33.3	0.0	0.0	33.3	33.3	14.3	0.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	75.0	83.3	19.2	7.7	100.0	100.0	14.3	0.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	16.7	16.7	11.5	11.5	66.7	66.7	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	8.3	8.3	0.0 (25)	7.7	0.0	16.7	7.7 (13)	7.1
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	66.7	58.3	0.0 (25)	3.9	33.3	33.3	0.0	0.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	66.7	75.0	7.7	30.8	33.3	33.3	0.0	0.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	8.3	8.3	7.7	7.7	66.7	66.7	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	83.3	83.3	11.5	15.4	33.3	66.7	14.3	0.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	75.0	66.7	19.2	7.7	33.3	33.3	7.1	0.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	16.7	16.7	0.0	0.0 (25)	66.7	66.7	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	100.0	100.0	100.0	96.2	100.0	66.7	100.0	100.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	83.3	83.3	50.0	57.7	83.3	66.7	35.7	50.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	91.7	83.3	15.4	42.3	66.7	66.7	0.0	28.6
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	41.7	33.3	0.0	19.2	0.0	16.7	0.0	7.1
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	50.0	50.0	15.4	11.5	16.7	16.7	14.3	7.1
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	58.3	50.0	7.7	7.7	33.3	33.3	0.0	0.0

Table A4.9 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive for *Plasmodium* spp. by blood immunological factor							
			Rheumatoid factor		Anti-nuclear antibodies		Anti-mouse antibodies		Rapid plasma reagin	
			Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=26)	Lot 2 (n=26)	Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=14)	Lot 2 (n=14)
Pf and Pv/Pvom										
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	66.7	58.3	0.0	0.0	33.3	50.0	0.0	0.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	66.7	58.3	8.0 (25)	12.5 (24)	33.3	16.7	15.4 (13)	7.1
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	58.3	66.7	0.0	7.7	100.0	66.7	0.0	0.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	75.0	83.3	69.2	84.6	66.7	33.3	64.3	64.3
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	75.0	83.3	11.5	7.7	100.0	66.7	0.0	0.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pan only										
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio. Inc.	16.7	25.0	0.0	0.0	33.3	33.3	0.0	0.0

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

Table A4.10: Phase-2 false-positive rate of pan, *P. vivax* or Pvom test line results in 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=118)	Lot 2 (n=118)	Overall (n=236)	Lot 1 (n=26)	Lot 2 (n=26)	Overall (n=52)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Avantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	NA	NA	NA	NA	NA	NA	NA	NA	NA
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan											
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	10.3 (117)	0.0 (117)	5.1 (234)	0.0	3.9	1.9	19.0	17.5 (57)	18.3 (115)
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	1.8 (113)	0.0	0.9 (231)	0.0	0.0	0.0	3.5	1.7	2.6
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0 (25)	0.0 (51)	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	6.8	2.5	4.7	0.0	0.0	0.0	8.6	10.3	9.5
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	7.7	3.9	15.5	8.6	12.1
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0	6.9	8.6	7.8
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	4.2	15.3	9.8	0.0	0.0	0.0	36.2	31.0	33.6
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	0.9	0.9	0.9	0.0	0.0	0.0	6.9	10.3	8.6
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0 (117)	0.0 (235)	0.0	3.9	1.9	3.6 (56)	8.6	6.1 (114)
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0 (117)	0.0	0.0 (235)	0.0	0.0	0.0	15.8 (57)	15.5	15.7 (115)
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	2.5	5.9	4.2	4.0 (25)	26.9	15.7 (51)	17.2	27.6	22.4
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.9 (117)	0.0	0.4 (235)	0.0	0.0 (25)	0.0 (51)	6.9	5.2	6.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	2.5	0.9	1.7	0.0	0.0	0.0	25.9	29.3	27.6
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	1.7	0.0	0.9	0.0	0.0	0.0	22.4	20.7	21.6
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0 (116)	0.0 (116)	0.0 (232)	0.0 (25)	0.0	0.0 (51)	10.3	10.5 (57)	10.4 (115)
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	87.2 (117)	68.6	77.9 (235)	100.0	100.0	100.0	100.0	93.1	96.6
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	3.4	5.1	4.2	0.0	0.0	0.0	27.6	31.0	29.3
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	4.2	5.1	4.7	0.0	0.0	0.0	32.8	29.3	31.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	0.0	0.0	3.9	1.9	8.6	13.8	11.2
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.9	0.4	3.9	0.0	1.9	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	11.9	9.3	10.6	3.9	11.5	7.7	20.7	19.0	19.8
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	1.7 (117)	0.0	0.9 (235)	0.0	0.0	0.0	19.0	17.2	18.1

Table A4.10 *(continued)*

Product	Catalogue number	Manufacturer	Percentage of false-positive pan test lines on "clean[a]" negative samples			Percentage of false-positive pan test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false-positive pan test lines on samples containing immunological factors[c]		
			Lot 1 (n=118)	Lot 2 (n=118)	Overall (n=236)	Lot 1 (n=26)	Lot 2 (n=26)	Overall (n=52)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf and Pv/Pvom											
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0 (117)	0.0	0.0 (235)	0.0 (25)	0.0	0.0 (51)	17.2	15.5	16.4
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	0.9 (115)	0.0 (117)	0.4 (232)	0.0 (23)	0.0 (23)	0.0 (46)	23.2 (56)	19.6 (56)	21.4 (112)
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	0.0 (114)	0.9	0.4 (232)	4.0 (25)	3.9	3.9 (51)	17.2	20.7	19.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	66.1	68.6	67.4	50.0	42.3	46.2	65.5	69.0	67.2
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	3.4	0.0	1.7	0.0	0.0	0.0	6.9	1.7	4.3
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	2.5	1.3	0.0	0.0	0.0	0.0	0.0	0.0
Pan only											
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	0.0	0.0	0.0	0.0	0.0	0.0	6.9	8.6	7.7

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[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

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

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			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 Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	14.0	1.0	1.0	14.0	1.0	1.0	14.0	0.0	1.0	15.0	0.0	1.0	14.0	0.0	1.0	13.0	1.0	1.0
Advantage P.f Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	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	15.0	0.0	2.0
CareStart™Malaria HRP2 (Pf)	G0141	Access Bio. Inc.	15.0	0.0	2.6	15.0	0.0	2.0	15.0	0.0	2.7	15.0	0.0	2.7	15.0	0.0	2.7	15.0	0.0	2.2
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	SSA Diagnostics & Biotech Systems	15.0	0.0	2.3	15.0	0.0	2.3	15.0	0.0	3.0	15.0	0.0	2.5	15.0	0.0	2.3	15.0	0.0	3.0
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	15.0	0.0	2.6	15.0	0.0	3.0	15.0	0.0	2.5	15.0	0.0	3.0	15.0	0.0	3.0	15.0	0.0	2.6
IMMUNOQUICK® MALARIA *falciparum*	0502_K25	BIOSYNEX	15.0	0.0	1.9	15.0	0.0	1.8	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	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	1.7	15.0	0.0	2.0
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	15.0	0.0	2.2	15.0	0.0	2.2	15.0	0.0	2.3	15.0	0.0	2.1	15.0	0.0	2.1	15.0	0.0	2.4
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	15.0	0.0	1.7	15.0	0.0	1.9	15.0	0.0	1.7	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.7
Pf and pan																				
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	10.0	0.0	1.2	15.0	0.0	1.0	10.0	0.0	1.3	12.0	0.0	1.0	0.0	0.0	ND	3.0	0.0	1.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	14.0	1.0	1.4	12.0	3.0	1.8	14.0	1.0	1.8	15.0	0.0	1.9	15.0	0.0	1.2	15.0	0.0	1.2
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. 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	15.0	0.0	1.9	15.0	0.0	1.8
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	15.0	0.0	2.9	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	14.0	0.0	1.7
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	15.0	0.0	2.0	15.0	0.0	2.0	14.0	0.0	1.9	15.0	0.0	2.0	14.0	0.0	1.8	13.0	0.0	1.2
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.1	15.0	0.0	2.7	14.0	0.0	1.9
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	15.0	0.0	2.7	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
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	15.0	0.0	1.7	15.0	0.0	2.0	15.0	0.0	1.1	15.0	0.0	1.9	14.0	1.0	1.0	15.0	0.0	1.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	1.8	15.0	0.0	2.0	15.0	0.0	1.5	15.0	0.0	1.4
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.8	15.0	0.0	1.0	15.0	0.0	1.9
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	15.0	0.0	1.4	15.0	0.0	1.3	15.0	0.0	1.0	15.0	0.0	1.3	14.0	0.0	1.0	14.0	0.0	1.0
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	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	1.9
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.3	15.0	0.0	1.7	15.0	0.0	1.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	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	1.9
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	0.0	0.0	ND	3.0	0.0	1.0	2.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	2.1	14.0	0.0	2.0	15.0	0.0	2.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	6.0	0.0	1.0	8.0	0.0	1.0	11.0	0.0	1.0	6.0	0.0	1.0	10.0	0.0	1.0	10.0	0.0	1.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	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
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	1.7	15.0	0.0	1.8	15.0	0.0	2.0	15.0	0.0	1.6
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	15.0	0.0	2.1	15.0	0.0	2.9	15.0	0.0	3.0	15.0	0.0	2.9	15.0	0.0	2.0	15.0	0.0	2.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	15.0	0.0	1.2	15.0	0.0	1.1	15.0	0.0	1.0	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	1.9

Table A4.11 *(continued)*

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	15.0	0.0	1.9	15.0	0.0	2.2	15.0	0.0	2.1	15.0	0.0	2.0	15.0	0.0	2.0	15.0	0.0	2.3
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	15.0	0.0	1.1	15.0	0.0	1.8	15.0	0.0	1.0	14.0	1.0	1.0	15.0	0.0	1.0	14.0	0.0	1.0
Pf and Pv/Pvom																				
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	15.0	0.0	1.1	15.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	1.1	8.0	0.0	1.0	11.0	0.0	1.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	10.0	1.0	2.0	15.0	0.0	2.0	12.0	1.0	2.0	15.0	0.0	1.9	12.0	1.0	1.8	13.0	1.0	1.8
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	15.0	0.0	2.0	15.0	0.0	1.9	15.0	0.0	1.7	15.0	0.0	1.9	15.0	0.0	2.0	15.0	0.0	2.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	15.0	0.0	2.2	15.0	0.0	2.3	15.0	0.0	2.1	15.0	0.0	2.2	15.0	0.0	2.9	15.0	0.0	2.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	15.0	0.0	1.9	15.0	0.0	1.0	14.0	0.0	1.1	15.0	0.0	1.1	14.0	0.0	1.0	15.0	0.0	1.9
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	15.0	0.0	1.9	15.0	0.0	1.9	15.0	0.0	1.9	14.0	0.0	2.0	15.0	0.0	2.0	13.0	0.0	1.5
Pan only																				
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	5.0	0.0	1.0	6.0	0.0	1.0	11.0	0.0	1.0	9.0	0.0	1.0	8.0	0.0	1.0	10.0	0.0	1.0
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0

ND, not determined

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] For pan-only tests

Table A4.11a: Heat stability testing results for pan test line of combination RDTs on a *P. falciparum* sample at low parasite density (20 parasites/µL). Positivity rate after 60 days at baseline (room temperature) and after incubation at 35 °C and 45 °C

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			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																				
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	1.0	0.0	1.0	0.0	0.0	ND	3.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0	1.0	ND	0.0	3.0	ND	0.0	1.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	10.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	1.0	13.0	0.0	1.0	0.0	0.0	ND	8.0	0.0	1.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	0.0	0.0	ND	0.0	0.0	ND	1.0	0.0	1.0	15.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	8.0	0.0	1.0	12.0	0.0	1.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	13.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0	11.0	0.0	1.0	9.0	0.0	1.0	7.0	0.0	1.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	0.0	0.0	ND	0.0	0.0	ND	2.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	ND
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	1.0	ND	0.0	0.0	ND
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	1.0	0.0	1.0	0.0	0.0	ND
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	ND	0.0	0.0	ND	3.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	1.0	0.0	2.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	4.0	0.0	1.3
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	0.0	0.0	ND	3.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	3.0	0.0	1.0	1.0	0.0	1.0	14.0	0.0	1.0	14.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	0.0	0.0	ND	0.0	0.0	ND	2.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	1.0	0.0	1.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	2.0	0.0	1.0	1.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	ND	4.0	0.0	1.0	0.0	0.0	ND
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	0.0	0.0	ND	0.0	0.0	ND	3.0	0.0	1.0	3.0	0.0	1.0	15.0	0.0	1.0	15.0	0.0	1.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	1.0	ND	0.0	0.0	ND	0.0	0.0	ND
Pf and Pv/Pvom																				
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

ND, not determined

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

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

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			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 Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	5.0	0.0	2.2	5.0	0.0	3.0	5.0	0.0	2.6	3.0	2.0	2.0	5.0	0.0	2.2	3.0	2.0	2.0
Advantage P.f Malaria Card	IR016025	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	3.8	5.0	0.0	4.0	5.0	0.0	4.0
CareStart™Malaria HRP2 (Pf)	G0141	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
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	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
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	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® MALARIA *falciparum*	0502_K25	BIOSYNEX	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	2.2	5.0	0.0	3.0	5.0	0.0	3.0
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering 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
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	Standard Diagnostics Inc.	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
Vision Malaria Pf	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
Pf and pan																				
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	5.0	0.0	2.6	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.6	5.0	0.0	2.4	5.0	0.0	1.8
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.6	5.0	0.0	3.0	5.0	0.0	3.6	5.0	0.0	3.0
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
Advantage Malaria Pan + Pf Card	IR231025	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	3.8	5.0	0.0	4.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	4.0	1.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.4
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	3.8
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	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
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	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
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.2
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	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
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	5.0	0.0	3.4	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.2	5.0	0.0	2.8
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.4	5.0	0.0	3.0	5.0	0.0	2.4
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	5.0	0.0	1.6	5.0	0.0	1.8	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	1.2	5.0	0.0	1.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	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	3.8
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (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	3.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0

(continued)

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

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	5.0	0.0	2.8	5.0	0.0	3.8	5.0	0.0	3.0	5.0	0.0	2.2	5.0	0.0	2.6	5.0	0.0	2.6
Pf and Pv/Pvom																				
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	2.8	5.0	0.0	3.0	5.0	0.0	2.2	5.0	0.0	2.0
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	4.0	1.0	3.3	5.0	0.0	3.6	3.0	1.0	3.0	4.0	1.0	3.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	5.0	0.0	3.2	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	3.0	5.0	0.0	3.0	5.0	0.0	3.0
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.6	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	4.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	5.0	0.0	3.2	5.0	0.0	3.8	5.0	0.0	3.6	5.0	0.0	4.0	4.0	0.0	4.0	5.0	0.0	4.0
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	5.0	0.0	3.8	5.0	0.0	4.0	5.0	0.0	4.0	5.0	0.0	3.4	5.0	0.0	4.0	5.0	0.0	4.0
Pan only																				
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	5.0	0.0	1.8	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	4.0	0.0	2.3	5.0	0.0	1.8
CareStart™Malaria pLDH (PAN)	G0111	Access Bio. Inc.	5.0	0.0	2.4	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0

ND, not determined

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] For pan-only tests

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 after 60 days at baseline (room temperature) and after incubation at 35 °C and 45 °C

Product	Catalogue number	Manufacturer	Baseline testing						35 °C						45 °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)		
			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																				
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	2.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	4.0	0.0	1.0	0.0	0.0	ND	3.0	0.0	1.0
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	4.0	0.0	1.0	3.0	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
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.6	5.0	0.0	2.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN INC.	4.0	1.0	2.0	5.0	0.0	2.0	5.0	0.0	1.0	5.0	0.0	1.6	5.0	0.0	1.0	5.0	0.0	1.0
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	Access Bio. Inc.	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.8	5.0	0.0	1.0
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	4.0	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	5.0	0.0	1.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	3.0	0.0	1.0	5.0	0.0	1.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	5.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	5.0	0.0	1.0	5.0	0.0	1.2	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	1.0	0.0	1.0	4.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	ND
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND	0.0	0.0	ND
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	5.0	0.0	1.0	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	4.0	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	4.0	0.0	1.0
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	5.0	0.0	1.0	5.0	0.0	1.6	5.0	0.0	1.0	5.0	0.0	1.4	5.0	0.0	1.0	4.0	0.0	1.0
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	4.0	1.0	1.0	5.0	0.0	1.2	5.0	0.0	1.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	4.0	0.0	1.0	2.0	0.0	1.5	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	5.0	0.0	1.0	5.0	0.0	2.0	5.0	0.0	2.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	4.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	5.0	0.0	1.2	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	5.0	0.0	1.0	5.0	0.0	1.0	3.0	0.0	1.0	3.0	0.0	1.0	5.0	0.0	1.0	5.0	0.0	1.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	Standard Diagnostics Inc.	5.0	0.0	1.0	5.0	0.0	1.6	5.0	0.0	1.8	5.0	0.0	1.8	5.0	0.0	1.0	5.0	0.0	2.0
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	3.0	0.0	1.0	3.0	0.0	1.0	5.0	0.0	1.0	1.0	0.0	1.0	0.0	0.0	ND	0.0	0.0	ND
Pf and Pv/Pvom																				
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

ND, not determined

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

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

Product	Catalogue number	Manufacturer	Baseline testing				35 °C				45 °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)	
			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 Pf Test	ITP11002TC1/TC40	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
Advantage P.f Malaria Card	IR016025	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
CareStart™ Malaria HRP2 (Pf)	G0141	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
diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	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
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC	Premier Medical Corporation	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® MALARIA *falciparum*	0502_K25	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
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf	05FK50/05FK53	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
Vision Malaria Pf	VB01	Vision Biotech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0
Pf and pan														
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) 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
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	1.0
Advantage Mal Card	IR221025	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
Advantage Malaria Pan + Pf Card	IR231025	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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN 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
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus 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
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	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
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody 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
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	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./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories 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
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	1.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	0.0	0.0	2.0	0.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (Pty) Ltd	2.0	0.0	4.0	0.0	2.0	0.0	4.0	0.0	4.0	0.0	2.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	1.0	0.0	1.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0	4.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	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
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	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			
			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
Pf and Pv/Pvom														
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical 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
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) 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
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	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
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pan only														
Advantage Pan Malaria Card	IR013025	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
CareStart™Malaria pLDH (PAN)	G0111	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

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

[a] For pan-only tests

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

Product	Catalogue number	Manufacturer	Baseline testing				35 °C				45 °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)	
			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														
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) 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
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.0	0.0	1.0	0.0	1.0
Advantage Mal Card	IR221025	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
Advantage Malaria Pan + Pf Card	IR231025	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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN 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
BioTracer™ Malaria Pf/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131	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
Clearview® Malaria Dual	VB20	Orgenics Ltd.(IS)	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
DIAQUICK Malaria *P.f/Pan* Cassette	Z11200CE	DIALAB GmbH	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0	0.0	0.0	2.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody 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
Genedia® Malaria *P.f/Pan* Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0	0.0
Humasis Malaria *P.f/Pan* Antigen Test	AMAL-7025	Humasis Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT Malaria Dual Test	ML03	ICT INTERNATIONAL	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./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories 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
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, INC.	3.0	0.0	0.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
MD Malaria Pf/Pan(pLDH) test	MDMALLDH001	Medical Diagnostech (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
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Pf/Pan Ag Rapid Test	R0113C	CTK Biotech Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid test for malaria Pan/Pf	50310025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	4.0	0.0	0.0	0.0	3.0	0.0	0.0	0.0
SD BIOLINE Malaria Antigen Pf/Pan	05FK60/05FK63	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
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	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/Pvom														
ASAN Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	Span Diagnostics Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Wondfo® One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species Pvom, *Plasmodium vivax, ovale* and *malariae*

Annex 5: Introducing RDT-based malaria diagnosis into national programmes

Introduction of parasite-based diagnosis at small clinics and at village level for case management poses many challenges, not only of logistics but also in managing the health-seeking and health-providing behaviour of patients and health workers. These can be addressed by a clear, time-bound strategic plan covering planning, implementation, monitoring and evaluation of the diagnosis programme, which must begin well before RDTs are procured. Furthermore, funding for the programme must include a significant component for planning and coordination, sensitization, information, education and communication, training, quality assurance, monitoring, supervision and logistics, in addition to procurement. In the absence of such funding, much of the expenditure on RDTs will be wasted, and loss of confidence in RDT-based diagnosis can hinder strengthening of appropriate malaria case management. A focal person or persons should be available to coordinate the overall implementation plan and to ensure that the various agencies involved understand the process and their own roles.

Examples of successful wide-scale introduction of malaria RDTs by various national programmes and comprehensive technical guidance on achieving universal access to malaria diagnostic testing have been reported (*1*,*2*). Figures A5.1 and A5.2 give examples of the steps and timelines for RDT implementation and budget components for a malaria diagnosis programme, respectively. These will have to be modified considerably for each programme.

Key challenges

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

Introducing RDTs will disprove this statement. To have an impact on malaria diagnosis and treatment, RDTs must be seen to provide an accurate diagnosis by both health workers and patients, that is, they must be as good or better than those relied on previously. A health worker requires a good alternative to antimalarial medicines for the management of parasite-negative febrile patients. To achieve and maintain confidence in RDT-based diagnosis, a good quality assurance system must be in place. There must be satisfactory education of health workers and widespread community sensitization. Health workers should have understanding of other causes of fever in order to devise appropriate management algorithms for parasite-negative cases.

Changing and enforcing regulatory requirements

At the national level, regulation might be required to control the importation and use of malaria RDTs, and new procedures for storage, distribution and inventory management, such as those used for medicines, might be necessary.

Figure A5.1. Example of malaria RDT implementation steps and timeline[a]

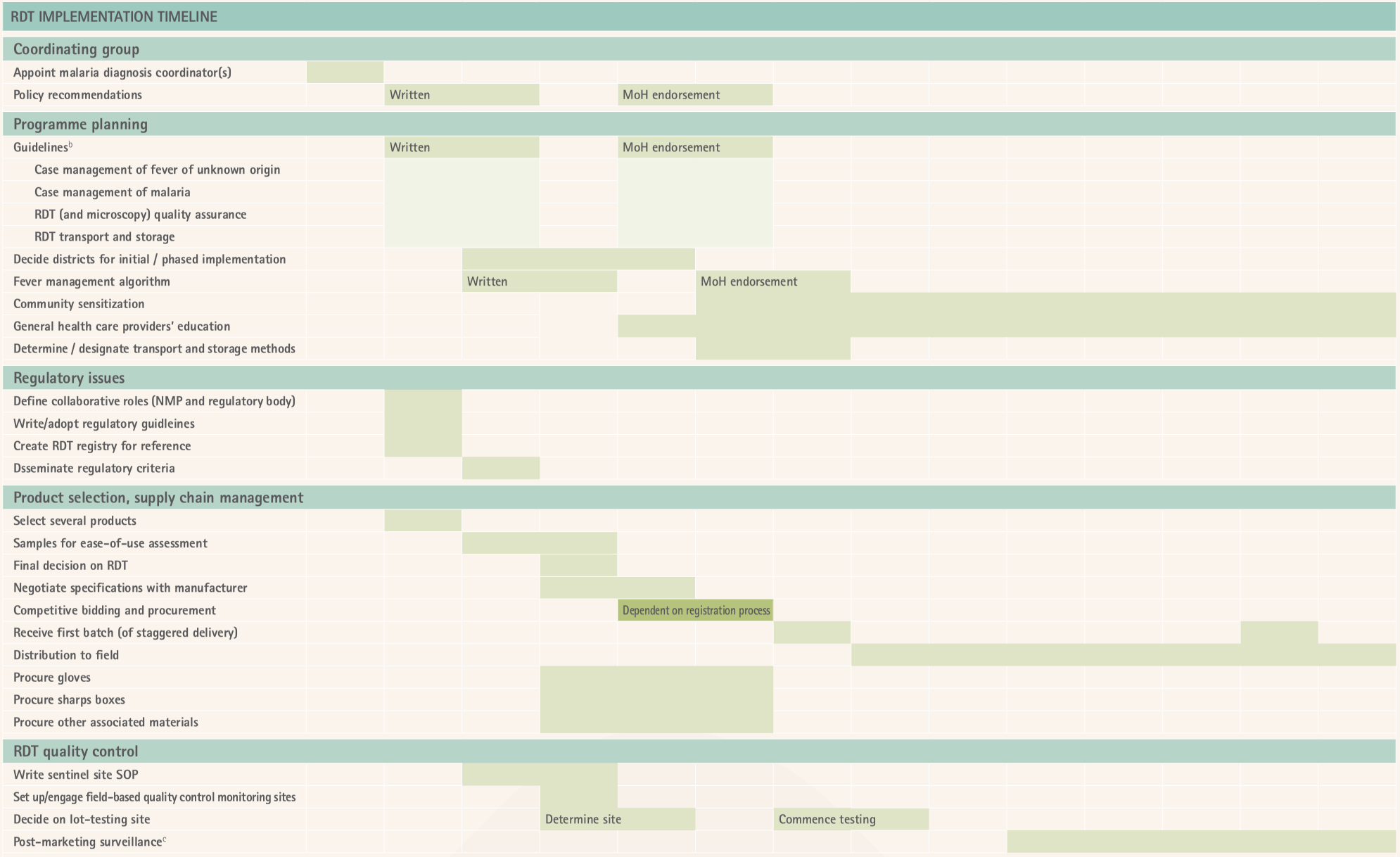
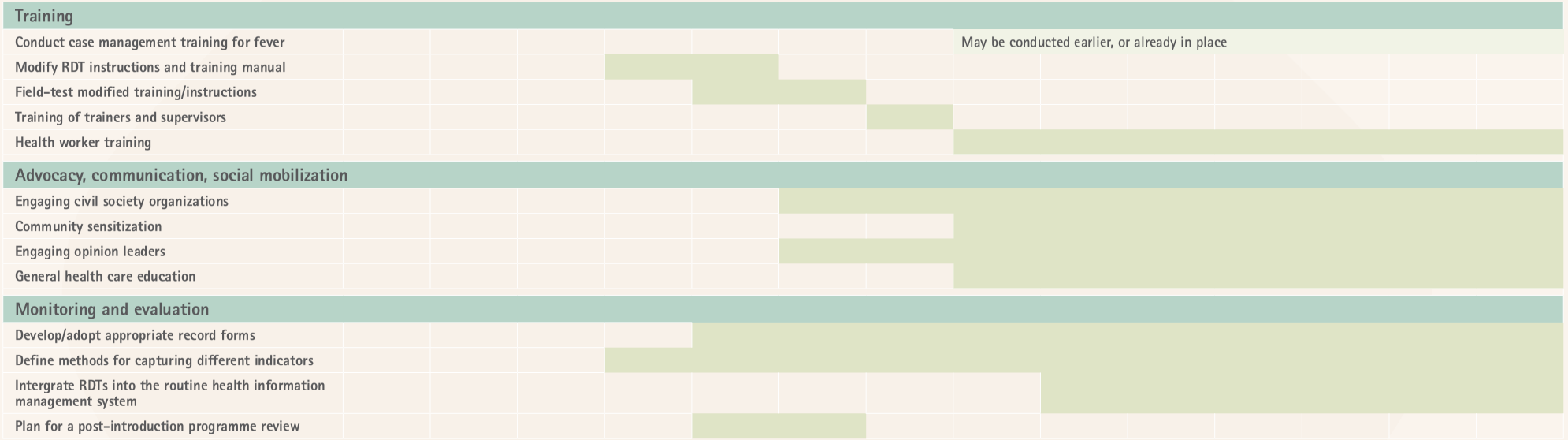


Figure A6.1 *(continued)*



MoH, ministry of health; NMP, national malaria programme

[a] Adapted with permission from FIND and Uganda National Malaria Control Programme

[b] May already be in place

[c] Sentinel site mciroscopy, possibly positive control wells in future

Figure A5.2. Components of the budget for a malaria diagnosis programme[a]

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

[a] Adapted with permission (*37*)

[b] For simplicity, activities specific to laboratories are listed under 'Microscopy', although both microscopy and RDT are generally performed in laboratories.

References

1. *Universal access to malaria diagnostic testing: an operational manual.* Geneva: World Health Organization; 2011.
2. Thiam S, Thior M, Faye B, et al. Major reduction in anti-malarial drug consumption in Senegal after nation-wide introduction of malaria rapid diagnostic tests. PLoS One 2011; 6: e18419.

NOTES

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