Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: round 6 (2014–2015)

World Health Organization

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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 3-6 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.

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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
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 1–6

1.1. Introduction

WHO estimates that 3.2 billion people are at risk for malaria. In 2014, there were an estimated 214 million cases (with an uncertainty range of 149 million to 303 million) and an estimated 438 000 deaths (with an uncertainty range of 236 000 to 635 000). Approximately 90% of all malaria deaths occur in sub-Saharan Africa, and nearly 70% occur in children under 5 years. Malaria remains endemic in 97 countries, and, while parasite-based diagnosis is increasing, approximately 35% of suspected malaria cases in Africa were not confirmed with a diagnostic test during 2014, 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.

RDT sales increased from 46 million sold in 2008 (before implementation of the product testing programme) to 314 million in 2014 (according to manufacturer sales data), when for the second time the number of diagnostic tests provided (RDTs and microscopy combined) exceeded the total number of courses of artemisinin-based combination therapy (ACT) administered in Africa. In 2014, it was confirmed that all the 97 countries with ongoing malaria transmission had adopted the WHO policy to test before administering treatment. Despite these achievements, a large number of cases remain undiagnosed, particularly within the private sector, indicating that there are still some gains to be made (*1*).

This summary presents an overview of the results of rounds 3–6 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 6. With the exception of products that are no longer manufactured and/or are delisted because of failure to comply with compulsory resubmission requirements, the results of all rounds of testing should be considered as a single data set. The separate, full reports of each round (*3–7*) 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 RDTs according to the ISO 13485:2003 quality system standard were invited to submit one to three products for evaluation. In each round of testing, products were evaluated against geographically diverse, cryopreserved *Plasmodium falciparum* and *P. vivax* clinical samples diluted to 200 and 2000 parasites/µL 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, 42 and 41 products from 13, 23, 27, 34 and 22 manufacturers were evaluated in rounds 2, 3, 4, 5 and 6, respectively. Of these 251 products, 247 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 rudimentary assessment of ease of use was made. In round 6, specific observations of RDT anomalies were also systematically recorded. Many manufacturers have decided voluntarily to submit products to

[1] See full reports of rounds 1–6 for lists of collaborating partners.

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 247 fully evaluated products in rounds 1–6, 36 have been evaluated twice, 12 have been evaluated three times, two evaluated four times and two evaluated five times. Of the 171 unique products tested in the programme, 45 detect *P. falciparum* alone, 115 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*), 10 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 (*8*) 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 1–5.

Of the 19 products due for compulsory retesting in round 6, two were submitted (Table S1). Round 2 products that were not 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 (*9*). 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 seventh round of product testing will begin in December 2015. The WHO Global Malaria Programme is currently assessing the impact of making WHO prequalification a requirement for procurement, including dossier and manufacture site assessment in addition to laboratory evaluation.

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 in blood to a low density (200 parasites/µL) and a higher 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 to reliably identify clinical malaria in many settings (*10*). For the purposes of this report, the main measure of performance is the panel detection score (PDS); for each RDT evaluated, the PDS is measured separately at the lower and the higher parasite densities. 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, which is 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.

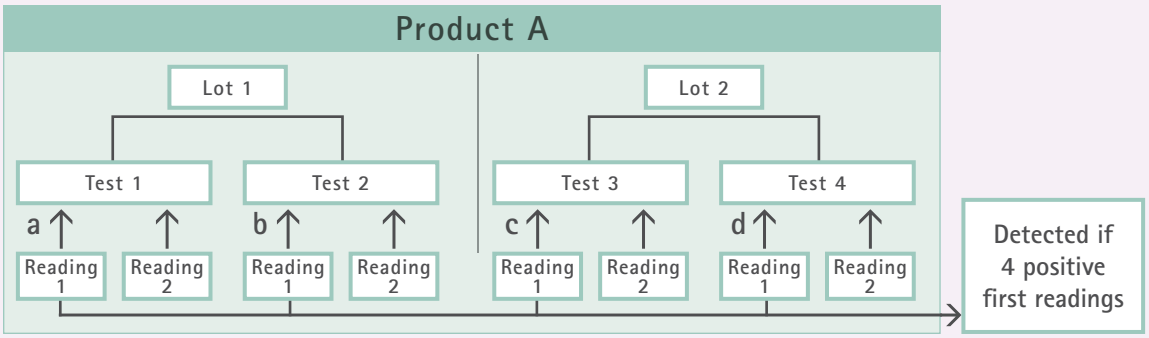
In general, as countries reduce the prevalence of malaria and even move towards malaria elimination, detection of low parasite densities becomes increasingly important in case management. As the high PDS at 2000 parasites/µL indicates, the sensitivity of many of these products is similar in populations with higher parasite densities; 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 (*11–12*). 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.

Heat stability (summarized in Table S3) is vital to maintaining the sensitivity of tests in the field. As a result, for

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.

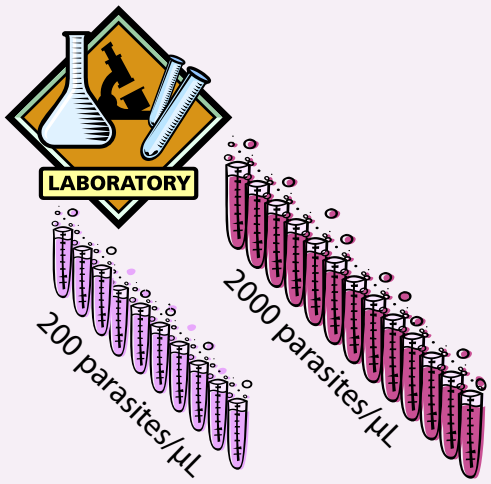
In the above example, the positivity rate is: 9/12 = 75%.

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.

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. Certain anomalies resulting from defects in production lots or RDT degradation may affect the running of the test or interpretation and may warrant a field safety notice and corrective action.

Detailed results can be found in the report of each evaluation (*3–7*) 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 6, the proportion of tests that achieved a PDS ≥ 75% at 200 parasites/µL is higher than all previous rounds for both *P. falciparum* (92.7%) and for *P. vivax*, (58.6%).

Several RDTs in the six 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.

All RDTs submitted to round 6 used the HRP2 antigen to detect *P. falciparum*, and all tests had a falciparum PDS that was < 100%. Three products were submitted that also detected Pf-pLDH. One product combined Pf-pLDH with HRP2 in the same test line, while the other two had dual test lines for detecting *P. falciparum*: one HPR2 test line and one Pf-pLDH test line. While both of the latter products performed well overall, the Pf-pLDH-detecting lines had considerably poorer performance than the HPR2-detecting test line, with a PDS of 36% and 52%, respectively. Thus, after six rounds of testing, the choice of well-performing pLDH-based *P. falciparum* tests remains limited, as it does for pan-only-specific tests.

The test performance of lots in round 6 did not vary much (Tables A3.1 and A4.1); in previous rounds, however, large variation has been found, confirming the advisability of testing lots after purchase and before use in the field. Anomalies that can interfere with test interpretation were recorded regularly during round 6, each product had between one and six different types of anomaly (Annex S2, Table 8, Fig. 30). The frequency of anomalies was recorded for the first time in round 6. Incomplete clearing and red background were the most common anomalies, seen in 95% and 85% of products, respectively. Cases of failed migration, incomplete migration and patchy broken test lines were the anomalies seen next most regularly, in 34%, 32% and 37% of products, respectively. Most products (29/41) had anomalies in < 5% of the tests; nine products had anomalies in 5–10% of tests and three had anomalies in 16–98% of all tests (Table 8).

All the RDTs evaluated in round 6 were in cassette format.

Only two of the 19 RDTs due for compulsory resubmission were retested, and both met the WHO procurement criteria on initial and repeat testing; however, both products had diminished performance on re-testing, with a decrease in PDS of 7% and 4% against *P. falciparum*. The combination RDT product showed a comparable PDS against *P. vivax* to that obtained at initial testing. Both products showed decreases of 3.0% and 1.6% in false-positive rates on re-testing.

1.5. Delisting of products in summary report

Manufacturers who choose not to submit products due for compulsory resubmission (every 5 years) are removed from the summary results listing (Tables S2 and S3) and the online interactive database (*13*) and are featured only in the full round-specific product testing report. They are also not eligible for WHO procurement. Furthermore, a product is delisted if WHO is notified by the manufacturer that its production has been discontinued. To date, 51 products have been delisted (Table S4).

1.6. 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 make 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* spp., 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 results in Table S2 indicate WHO prequalification status and are colour-coded to reflect achievement of WHO

[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 *Nora.Champouillon@finddx.org*.

performance requirements for RDT procurement. 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 (*13*). This online database has been updated to allow filtering of results by RDT procedural characteristics, such as blood volume requirements, number of buffer drops and time to a result. This will allow identification of products with similar procedures so that, when product replacement is required, another product can be selected with the same or a similar protocol. Use of similar products may reduce the need for user retraining and reduce user error.

Comprehensive guidance on several aspects of procurement can be found in *Good practices for selecting and procuring rapid diagnostic tests for malaria* (*14*) and guidance on implementation in *Universal access to malaria diagnosis* (*15*).

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

In the WHO programme for prequalification of diagnostics and medical devices, the results of product testing are used 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, as it may become a requirement for WHO procurement in the future. Prequalified RDTs are listed in summary tables and at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/*.

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.

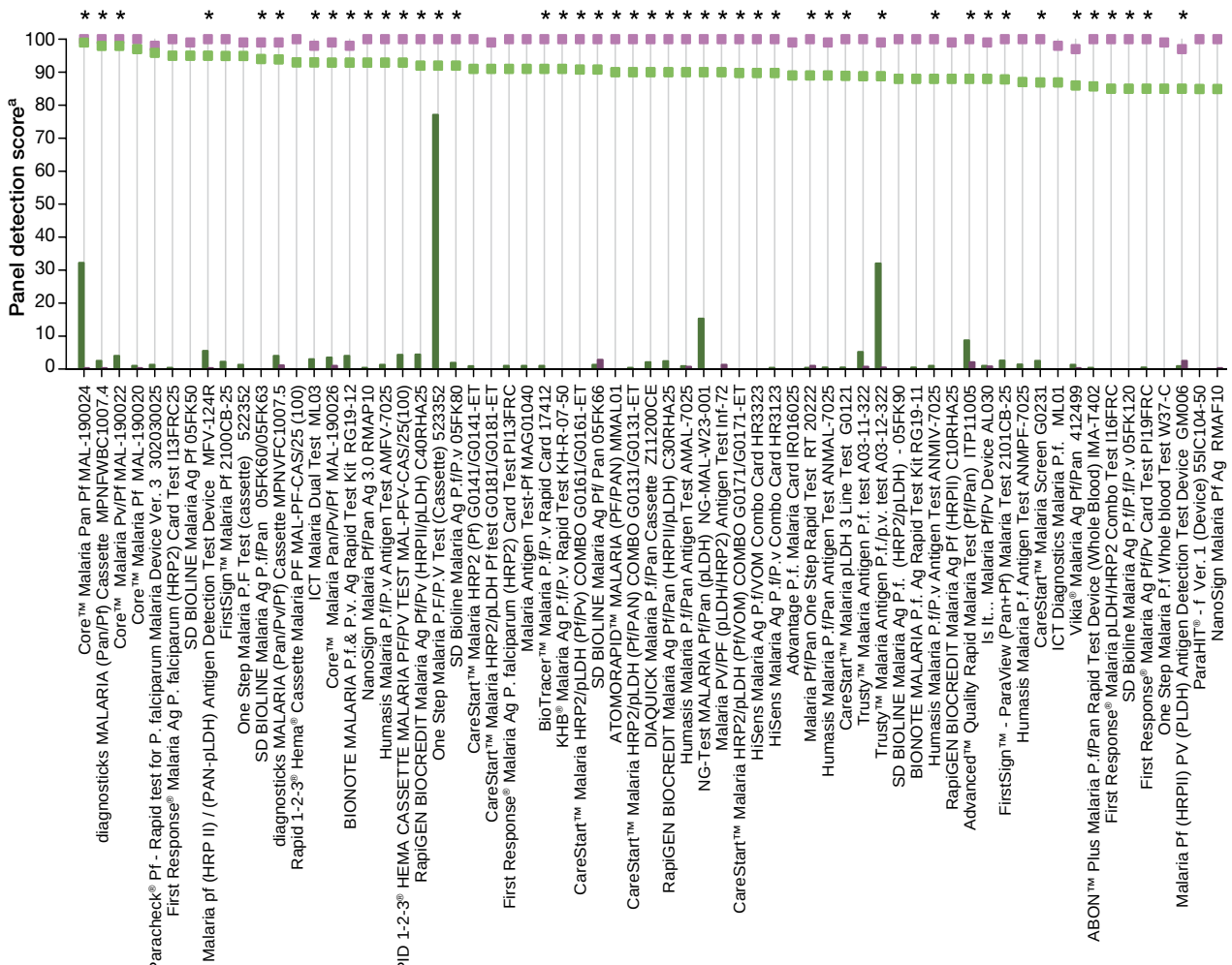
(B) For the detection of *Plasmodium vivax* (Pv) in all transmission settings the panel detection score (PDS) against Pv samples should be at least 75% at 200 parasites/µL.

(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 3–6 against wild-type (clinical) samples containing *P. falciparum* 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 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

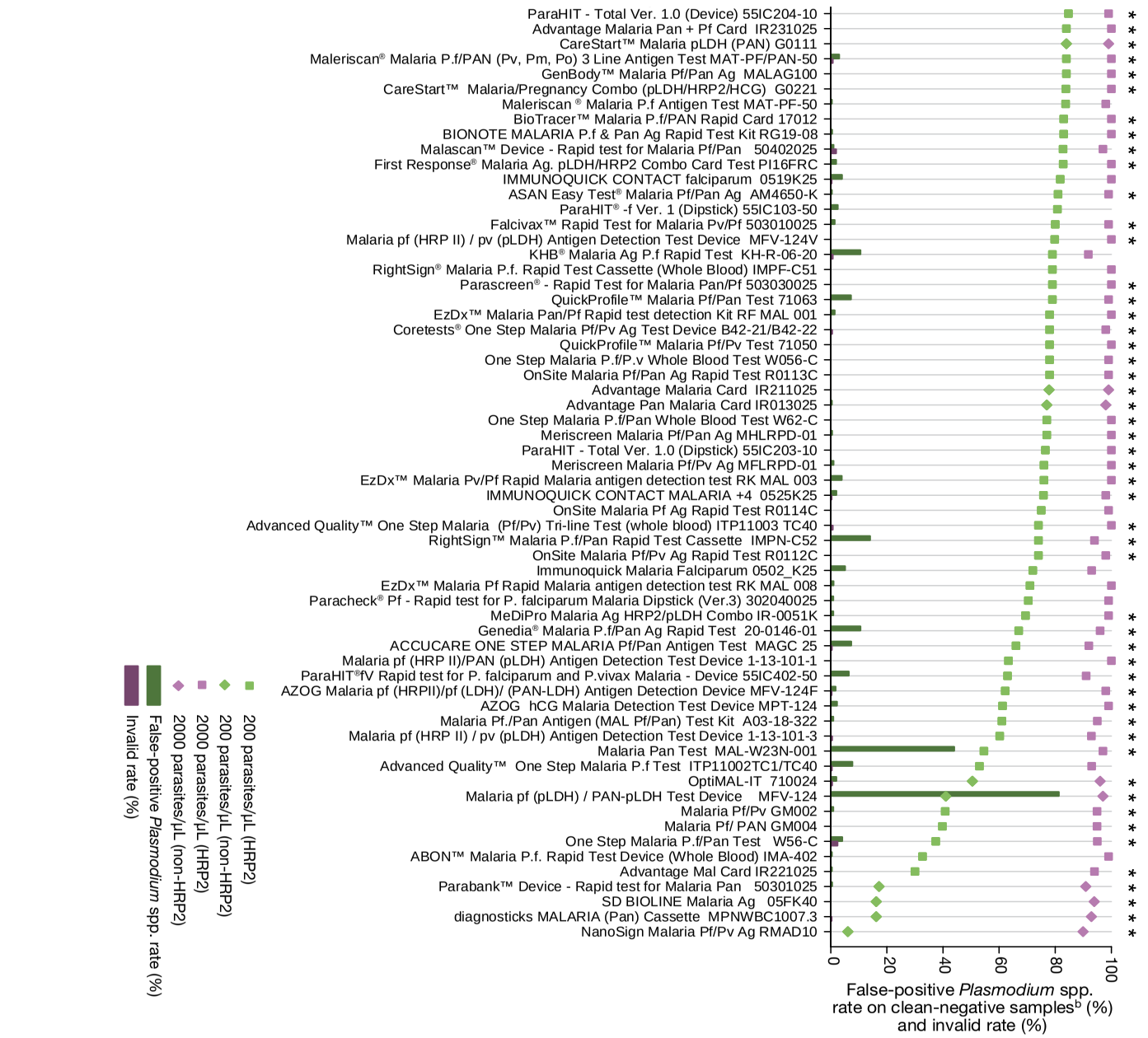
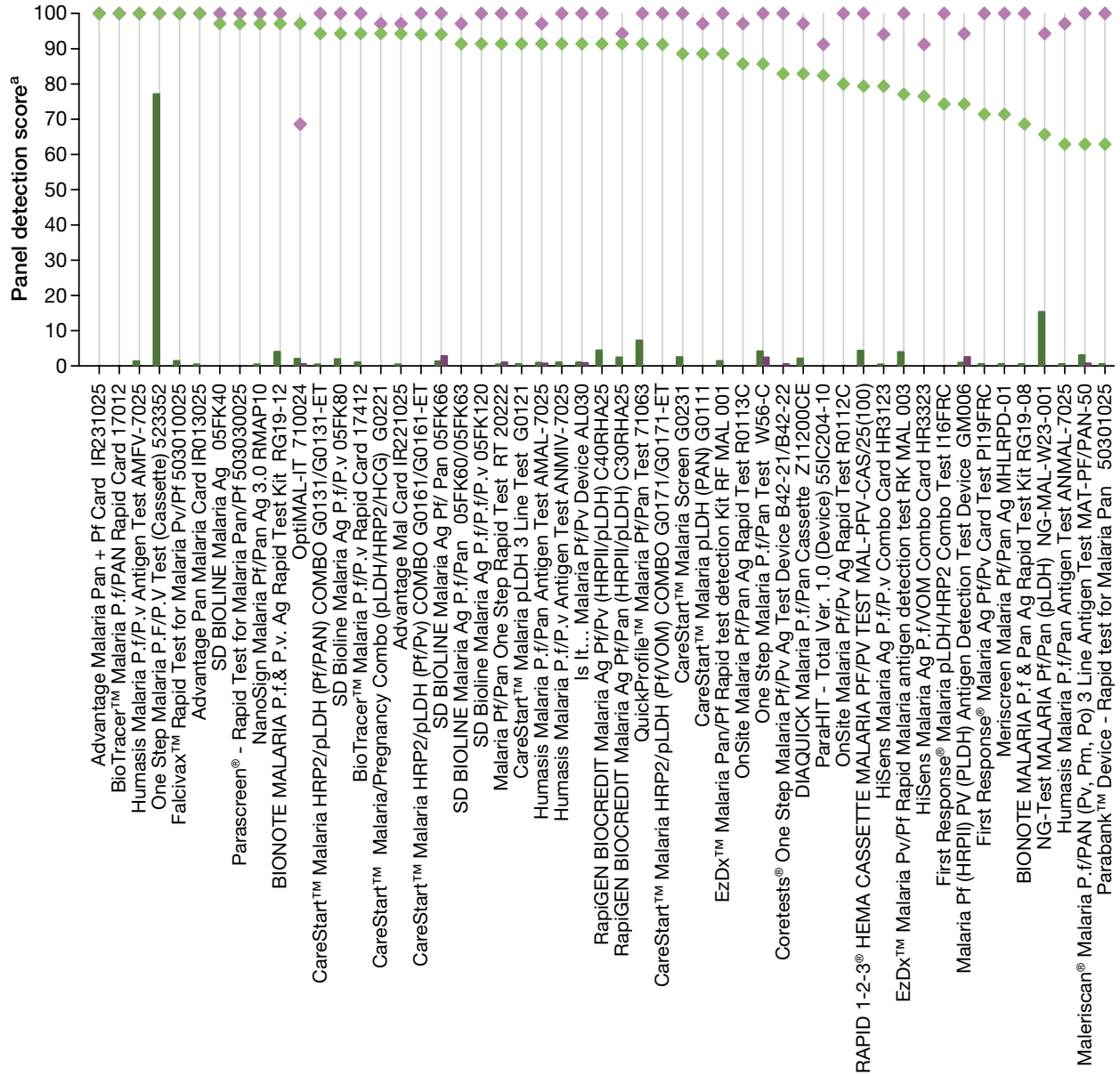

ParaHIT - Total Ver. 1.0 (Device) 55IC204-10
Advantage Malaria Pan + Pf Card IR231025
CareStart™ Malaria pLDH (PAN) G0111
Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test MAT-PF/PAN-50
GenBody™ Malaria Pf/Pan Ag MALAG100
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) G0221
Maleriscan ® Malaria P.f Antigen Test MAT-PF-50
BioTracer™ Malaria P.f/PAN Rapid Card 17012
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit RG19-08
Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test PI16FRC
IMMUNOQUICK CONTACT falciparum 0519K25
ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
ParaHIT® -f Ver. 1 (Dipstick) 55IC103-50
Falcivax™ Rapid Test for Malaria Pv/Pf 503010025
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
KHB® Malaria Ag P.f Rapid Test KH-R-06-20
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood) IMPF-C51
Parascreen® - Rapid Test for Malaria Pan/Pf 503030025
QuickProfile™ Malaria Pf/Pan Test 71063
EzDx™ Malaria Pan/Pf Rapid test detection Kit RF MAL 001
Coretests® One Step Malaria Pf/Pv Ag Test Device B42-21/B42-22
QuickProfile™ Malaria Pf/Pv Test 71050
One Step Malaria P.f/P.v Whole Blood Test W056-C
OnSite Malaria Pf/Pan Ag Rapid Test R0113C
Advantage Malaria Card IR211025
Advantage Pan Malaria Card IR013025
One Step Malaria P.f/Pan Whole Blood Test W62-C
Meriscreen Malaria Pf/Pan Ag MHLRPD-01
ParaHIT - Total Ver. 1.0 (Dipstick) 55IC203-10
Meriscreen Malaria Pf/Pv Ag MFLRPD-01
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test RK MAL 003
IMMUNOQUICK CONTACT MALARIA +4 0525K25
OnSite Malaria Pf Ag Rapid Test R0114C
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood) ITP11003 TC40
RightSign™ Malaria P.f/Pan Rapid Test Cassette IMPN-C52
OnSite Malaria Pf/Pv Ag Rapid Test R0112C
Immunoquick Malaria Falciparum 0502_K25
EzDx™ Malaria Pf Rapid Malaria antigen detection test RK MAL 008
Paracheck® Pf - Rapid test for P. falciparum Malaria Dipstick (Ver.3) 302040025
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
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
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
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
Advantage Mal Card IR221025
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
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µL (HRP2)
200 parasites/µL (non-HRP2)
2000 parasites/µL (HRP2)
2000 parasites/µL (non-HRP2)
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S2: Malaria RDT performance in phase 2 of rounds 3–6 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000 or 5000) parasite density (parasites/µL) and clean-negative samples

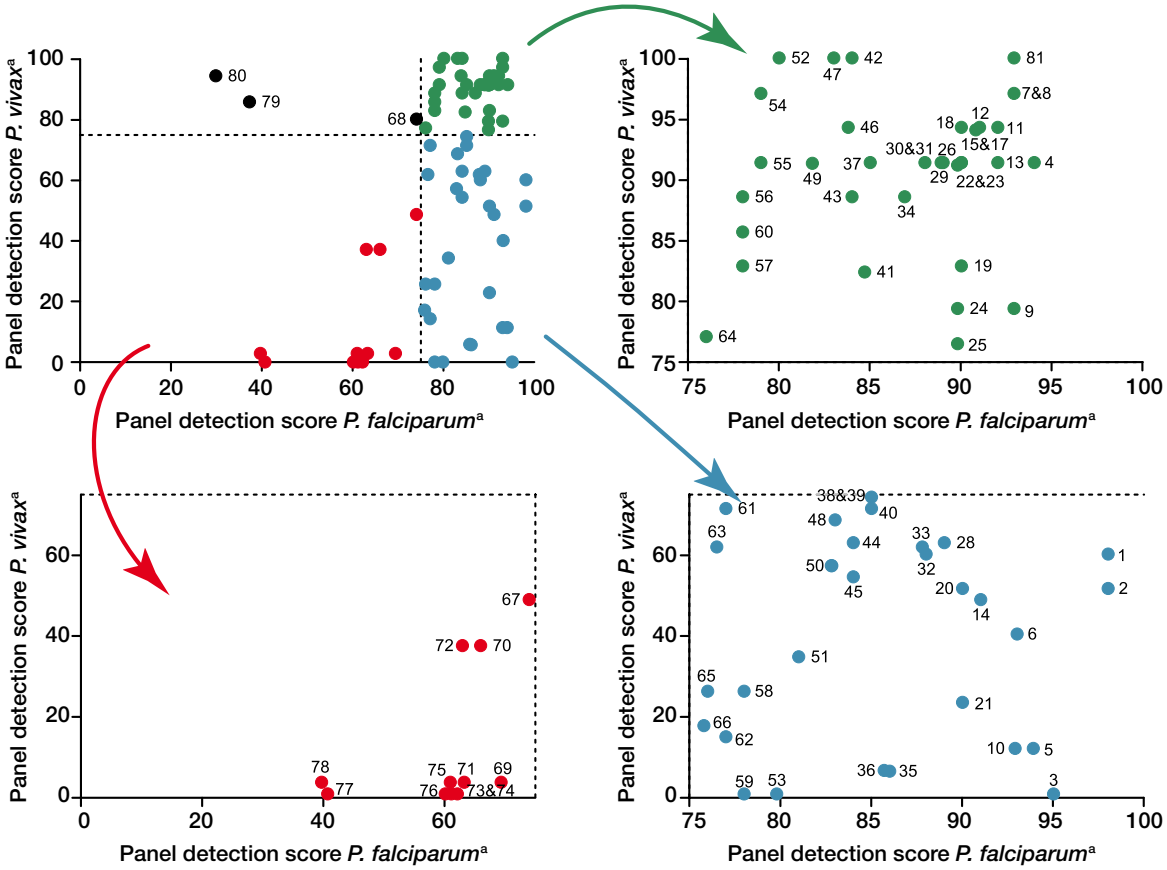


[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

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


FirstSign™ - ParaView (Pan+Pf) Malaria Test 2101CB-25
ParaHIT - Total Ver. 1.0 (Dipstick) 55IC203-10
Core™ Malaria Pv/Pf MAL-190022
Advanced™ Quality Rapid Malaria Test (Pf/Pan) ITP11005
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test PI16FRC
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
Malaria PV/PF (pLDH/HRP2) Antigen Test Inf-72
KHB® Malaria Ag P.f/P.v Rapid Test KH-R-07-50
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood) ITP11003 TC40
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
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
Core™ Malaria Pan Pf MAL-190024
QuickProfile™ Malaria Pf/Pv Test 71050
Meriscreen Malaria Pf/Pv Ag MFLRPD-01
ATOMORAPID™ MALARIA (PF/PAN) MMAL01
IMMUNOQUICK CONTACT MALARIA +4 0525K25
Genedia® Malaria P.f/Pan Ag Rapid Test 20-0146-01
One Step Malaria P.f/Pan Whole Blood Test W62-C
diagnosticks MALARIA (Pan/Pv/Pf) Cassette MPNVFC1007.5
Core™ Malaria Pan/Pv/Pf MAL-190026
Malaria pf (pLDH) / PAN-pLDH Test Device MFV-124
NanoSign Malaria Pf/Pv Ag RMAD10
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) IMA-T402
Vikia® Malaria Ag Pf/Pan 412499
MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
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 MFV-124R
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
One Step Malaria P.f/P.v Whole Blood Test W056-C
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
AZOG hCG Malaria Detection Test Device MPT-124
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
Malaria Pan Test MAL-W23N-001
Malaria Pf/Pv GM002
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 RDTs meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 3–6 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low parasite density (200 parasites/µL)



1 Core™ Malaria Pv/Pf MAL-190022
2 diagnosticks MALARIA (Pan/Pf) Cassette MPNFWBC1007.4
3 Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device MFV-124R
4 SD BIOLINE Malaria Ag P.f/Pan 05FK60/05FK63
5 diagnosticks MALARIA (Pan/Pv/Pf) Cassette MPNVFC1007.5
6 ICT Malaria Dual Test ML03
7 NanoSign Malaria Pf/Pan Ag 3.0 RMAP10
8 BIONOTE MALARIA P.f.& P.v. Ag Rapid Test Kit RG19-12
9 RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST MAL-PFV-CAS/25(100)
10 Core™ Malaria Pan/Pv/Pf MAL-190026
11 SD Bioline Malaria Ag P.f/P.v 05FK80
12 BioTracer™ Malaria P.f/P.v Rapid Card 17412
13 RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) C40RHA25
14 KHB® Malaria Ag P.f/P.v Rapid Test KH-R-07-50
15 CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO G0161/G0161-ET
17 SD BIOLINE Malaria Ag Pf/ Pan 05FK66
18 CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO G0131/G0131-ET
19 DIAQUICK Malaria P.f/Pan Cassette Z11200CE
20 Malaria PV/PF (pLDH/HRP2) Antigen Test Inf-72
21 ATOMORAPID™ MALARIA (PF/PAN) MMAL01
22 CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO G0171/G0171-ET
23 Humasis Malaria P.f/Pan Antigen Test AMAL-7025
24 HiSens Malaria Ag P.f/P.v Combo Card HR3123
25 HiSens Malaria Ag P.f/VOM Combo Card HR3323
26 Malaria Pf/Pan One Step Rapid Test RT 20222
27 RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) C30RHA25
28 Humasis Malaria P.f/Pan Antigen Test ANMAL-7025
29 CareStart™ Malaria pLDH 3 Line Test G0121
30 Humasis Malaria P.f/P.v Antigen Test ANMIV-7025
31 Is It… Malaria Pf/Pv Device AL030
32 Advanced™ Quality Rapid Malaria Test (Pf/Pan) ITP11005
33 FirstSign™ - ParaView (Pan+Pf) Malaria Test 2101CB-25
34 CareStart™ Malaria Screen G0231
35 Vikia® Malaria Ag Pf/Pan 412499
36 ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) IMA-T402
37 SD Bioline Malaria Ag P.f/P.f/P.v 05FK120
38 First Response® Malaria pLDH/HRP2 Combo Test I16FRC
39 Malaria Pf (HRPII) PV (PLDH) Antigen Detection Test Device GM006
40 First Response® Malaria Ag Pf/Pv Card Test PI19FRC
41 ParaHIT - Total Ver. 1.0 (Device) 55IC204-10
42 Advantage Malaria Pan + Pf Card IR231025
43 CareStart™ Malaria pLDH (PAN) G0111
44 Maleriscan® Malaria P.f/PAN (Pv, Pm, Po) 3 Line Antigen Test MAT-PF/PAN-50
45 GenBody™ Malaria Pf/Pan Ag MALAG100
46 CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG) G0221
47 BioTracer™ Malaria P.f/PAN Rapid Card 17012
48 BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit RG19-08
49 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test PI16FRC
50 Malascan™ Device - Rapid test for Malaria Pf/Pan 50402025
51 ASAN Easy Test® Malaria Pf/Pan Ag AM4650-K
52 Falcivax™ Rapid Test for Malaria Pv/Pf 503010025
53 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device MFV-124V
54 Parascreen® - Rapid Test for Malaria Pan/Pf 503030025
55 QuickProfile™ Malaria Pf/Pan Test 71063
56 EzDx™ Malaria Pan/Pf Rapid test detection Kit RF MAL 001
57 Coretests® One Step Malaria Pf/Pv Ag Test Device B42-21/B42-22
58 QuickProfile™ Malaria Pf/Pv Test 71050
59 One Step Malaria P.f/P.v Whole Blood Test W056-C
60 OnSite Malaria Pf/Pan Ag Rapid Test R0113C
61 Meriscreen Malaria Pf/Pan Ag MHLRPD-01
62 One Step Malaria P.f/Pan Whole Blood Test W62-C
63 ParaHIT - Total Ver. 1.0 (Dipstick) 55IC203-10
64 EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test RK MAL 003
65 Meriscreen Malaria Pf/Pv Ag MFLRPD-01
66 IMMUNOQUICK CONTACT MALARIA +4 0525K25
67 Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood) ITP11003 TC40
68 OnSite Malaria Pf/Pv Ag Rapid Test R0112C
69 MeDiPro Malaria Ag HRP2/pLDH Combo IR-0051K
70 ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test MAGC 25
71 Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device 1-13-101-1
72 ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device 55IC402-50
73 AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device MFV-124F
74 AZOG hCG Malaria Detection Test Device MPT-124
75 Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit A03-18-322
76 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device 1-13-101-3
77 Malaria Pf/Pv GM002
78 Malaria Pf/ PAN GM004
79 One Step Malaria P.f/Pan Test W56-C
80 Advantage Mal Card IR221025
81 Humasis Malaria P.f/P.v Antigen Test AMFV-7025

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

Table S1: Product resubmissions: WHO malaria RDT product testing rounds 1–6

Manufacturer	Product name	Product code	Product re-submission Round	
			Voluntary	Compulsory
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161/G0161-ET	2, 4	
	CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171/G0171-ET	2, 4	
	CareStart™Malaria HRP2 (Pf)	G0141/G0141-ET	1	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	G0131/G0131-ET	1	5
	CareStart™Malaria pLDH (PAN)	G0111	1	5
	CareStart™Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	2	6
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	4, 5, 6	
ARKRAY Healthcare Pvt. Ltd.[a]	ParaHIT® - f (Device)[b]	55IC102-10	1, 3	
	ParaHIT® - f (Dipstick)[c]	55IC101-10	1, 3	
AZOG	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device[d]	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	
Bionote, Inc.	BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	3, 6	
	BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	3, 6	
Biosynex	IMMUNOQUICK® MALARIA falciparum	0502_K25	1	5
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f/PAN Rapid Card	17012	5, 6	
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, 6	
	Onsite Malaria Pf/Pan Malaria Ag Rapid Test	R0113C	2, 3, 4, 5, 6	
	Onsite Malaria Pf/Pv Ag Rapid Test	R0112C	2, 3, 4, 6	
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/P.v Whole Blood Test	W056-C	5, 6	
	One Step Malaria P.f Test[e]	W37-C	2, 3, 4, 6	
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	4, 5	
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
	Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	3, 6	
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)[f]	30301025	1, 3, 4	
	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver.3)[f]	30302025	1, 3, 4	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[g]	I16FRC25	1, 2, 5	
	First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC25	1	5
RapiGEN Inc.	RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	5, 6	
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	1, 3, 5	
	SD BIOLINE Malaria Antigen	05FK50	1	5
	SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	3, 6	
	SD Bioline Malaria Ag P.f/P.v	05FK80	2	6
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[h]	1, 3	
	Malaria Rapid Pf /Clearview® Malaria Pf	VB01	1, 3, 5	
	Malaria Rapid Dual/Clearview® Malaria Dual Test Device	VB20[h]	1, 3, 5	
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	1, 3	
	Parabank™ Device - Rapid test Malaria Pan	50301025	1, 3	
	Parascreen™ Device - Rapid test for Malaria Pan/Pf	50310025; 503030025 (rd 6)	1, 3, 4, 5, 6	
	Falcivax™ Rapid Test for Malaria Pv/Pf (device)	50300025; 503010025 (rd 6)	2, 4, 6	

[a] Span Diagnostics Ltd. is now ARKRAY Healthcare Pvt.Ltd.

[b] In round 1 product name and catalogue number was Parahit-f TEST DEVICE FOR FALCIPARUM MALARIA (25975)

[c] In round 1 product name and catalogue number was Parahit-f DIPSTICK FOR FALCIPARUM MALARIA (25977)

[d] 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.

[e] In round 2, product did not pass phase 1, therefore results do not feature in summary tables.

[f] Ver.3 was introduced after round 1

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

[h] 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 3–6 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000 or 5000) parasite density (parasites/µL) and clean-negative samples

Product	Product code	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples			
							Pf samples	Pv samples	Pf samples	Pv samples				
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]			
Pf only														
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0	NA	0.0	0.4	0.0	4	No
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	5	No
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	5	Yes
BIONOTE MALARIA P.f. Ag Rapid Test Kit[j]	RG19-11	Bionote,Inc.	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.5	0.0	6	Yes
CareStart™ Malaria HRP2 (Pf)	G0141[m]/G0141-ET	Access Bio, Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	5	Yes[m]
CareStart™ Malaria HRP2/pLDH Pf test[j]	G0181[m]/G0181-ET	Access Bio, Inc.	91.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
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	Yes
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	71.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.1	6	No
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	95.0	NA	100.0	NA	NA	0.7	NA	0.0	0.4	0.0	5	Yes[m]
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.0	6	Yes
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.5	2.2 (231)	0.2	4	Yes
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	100.0	NA	NA	1.4	NA	1.4	1.4	0.0	6	Yes
ICT Diagnostics Malaria P.f.	ML01	ICT INTERNATIONAL	86.9	NA	98.0	NA	NA	0.0	NA	0.0	0.0	0.0	3	Yes
IMMUNOQUICK CONTACT falciparum	0519K25	Biosynex	81.8	NA	100.0	NA	NA	3.6 (139)	NA	1.4	4.0 (199)	0.3	3	Yes
IMMUNOQUICK® MALARIA falciparum	0502_K25	Biosynex	72.0	NA	93.0	NA	NA	3.6	NA	4.3	5.1 (234)	0.2	5	No
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	No
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	91.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.0	6	Yes
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	Yes
NanoSign Malaria Pf Ag	RMAF10	Bioland, Ltd	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.3	3	Yes
One Step Malaria P.f Whole blood Test[j]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	6	Yes
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0	NA	1.5	1.3	0.0	4	Yes
OnSite Malaria Pf Ag Rapid Test[j]	R0114C	CTK Biotech, Inc.	75.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.2	6	Yes
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	302030025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0	NA	0.0	1.3	0.0	4	Yes
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0	NA	0.0	0.9	0.0	4	No
ParaHIT® - f Ver. 1 (Device)	55IC104-50	ARKRAY Healthcare Pvt. Ltd.[n]	84.9	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	3	Yes[m]
ParaHIT® - f Ver. 1 (Dipstick)	55IC103-50	ARKRAY Healthcare Pvt. Ltd.[n]	80.8	NA	99.0	NA	NA	0.0	NA	1.4	2.5	0.0	3	Yes[m]
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	100.0	NA	NA	2.9 (139)	NA	0.0	0.0	0.2	6	Yes
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	99.0	NA	NA	0.7	NA	0.0	0.5 (207)	0.2	6	Yes
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	6	Yes
SD Bioline Malaria Ag P.f (HRP2/pLDH)[j,k]	05FK90	Standard Diagnostics, Inc.	88.0	NA	100.0	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	95.0	NA	99.0	NA	NA	0.0	NA	2.9	0.0	0.0	5	Yes[m]
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.9	5.2 (230)	0.7	4	Yes
Pf and pan														
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0	4	No
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	No
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	No
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	5	No
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	Yes
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	90.0	22.9	100.0	97.1	0.0 (399)	2.9	0.0	0.0	0.0 (207)	0.2	6	No

Table S2 *(continued)*

Product	Product code	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples	False-positive *Plasmodium* spp. Infection[l]			
							False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]				
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	No
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit[j]	RG19-08	BioNote, Inc.	83.0	68.6	100.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0	6	No
BioTracer™ Malaria P.f/PAN Rapid Card[j]	17012	Bio Focus Co., Ltd.	83.0	100.0	100.0	100.0	4.0	0.0	0.0	0.0	0.0	0.0	6	Yes
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	Yes
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131[m]/G0131-ET	Access Bio, Inc.	90.0	94.3	100.0	100.0	1.5	0.7	0.0	0.0	0.4	0.0	5	Yes[m]
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	Yes
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	Yes
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	No
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	98.0	51.4	100.0	97.1	0.0 (394)	0.0	0.0	0.0 (69)	2.5	0.3	3	No
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	Yes
EzDx™ Malaria Pan/Pf Rapid test detection Kit[j]	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	100.0	100.0	0.3	0.0	0.0	0.0	1.4	0.0	6	Yes
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	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	No
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	100.0	100.0	1.5	0.0	0.0	0.0	1.9 (207)	0.1	6	Yes
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0	4	No
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	No
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	No
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	Yes
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	89.0	62.9	99.0	97.1	0.0	0.7 (139)	0.0	1.4	0.5	0.1	6	No
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	5	No
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	No
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	88.0	91.4	99.0	100.0	0.5 (395)	0.0	0.0	0 (68)	1.0 (206)	0.8	6	Yes
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	No
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 (3.98)	4.3	0.0 (199)	0.0	0.9	0.2	5	No
Malaria pf (HRP II) / (PAN-pLDH) Antigen Detection Test Device	MFV-124R	AZOG, Inc.	95.0	0.0	100.0	94.3	0.0 (395)	7.9	8.1	0.0	5.5 (199)	0.3	3	No
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	No
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	5	No
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	No
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	Yes
Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	Zephyr Biomedical Systems	82.8	57.1	97.0	100.0	1.0 (392)	0.7 (136)	1.0 (194)	0.0 (68)	1.0 (195)	1.9	3	No
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	No
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	77.0	71.4	100.0	100.0	1.3	0.0	0.0	0.0	0.5	0.0	6	No
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland, Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0	4	Yes
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	No
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	No
One Step Malaria P.f/Pan Test	W56-C	Guangzhou Wondfo Biotech Co. Ltd.	37.4	85.7	95.0	100.0	8.4 (383)	0.0 (137)	0.0 (194)	0.0 (68)	4.1 (195)	2.4	3	No
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	77.0	14.3	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	6	No
OnSite Malaria Pf/Pan Ag Rapid Test[j]	R0113C	CTK Biotech, Inc.	78.0	85.7	99.0	97.1	0.0 (398)	0.0	0.5	1.4	0.0 (207)	0.2	6	Yes
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	No
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	ARKRAY Healthcare Pvt. Ltd.[n]	84.7	82.4	99.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1	4	Yes
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	ARKRAY Healthcare Pvt. Ltd.[n]	76.5	61.8	100.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0	4	No
Parascreen® - Rapid Test for Malaria Pan/Pf[j]	503030025	Zephyr Biomedicals	79.0	97.1	100.0	100.0	2.3	0.0	0.0	0.0	0.0	0.0	6	Yes
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	99.0	100.0	6.5	1.4	0.5 (199)	0.0	7.2	0.1	6	Yes

(continued)

Table S2: Malaria RDT phase-2 performance in rounds 3–6 against wild-type (clinical) samples containing *P. falciparum* (Pf) and *P. vivax* (Pv) at low (200) and high (2000 or 5000) parasite density (parasites/µL) and clean-negative samples *(continued)*

Product	Product code	Manufacturer	Panel detection score[a]				False-positive rates (%)				Total false-positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µL		2000 or 5000 parasites/µL		200 parasites/µL		2000 or 5000 parasites/µL		Clean-negative samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples				
							False-positive non-Pf infection[e]	False-positive Pf infection[f]	False-positive non-Pf infection[g]	False-positive Pf infection[h]	False-positive *Plasmodium* spp. Infection[i]			
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	90.0	91.4	100.0	94.3	0.0 (399)	0.0	0.0	2.9	2.4 (207)	0.1	6	Yes
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	No
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	94.0	91.4	99.0	97.1	0.8	0.7	0.5	1.4	0.0	0.0	5	Yes[m]
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	Yes
SD BIOLINE Malaria Ag	05FK40	Standard Diagnostics Inc.	16.2	97.1	93.9	100.0	0.8	0.0	0.0	0.0	0.0	0.0	3	No
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	No
Pf and Pv/Pvom														
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)[j]	ITP11003 TC40	InTec Products, Inc.	74.0	48.6	100.0	100.0	0.0 (396)	0.0	0.0 (199)	0.0 (69)	0.0 (207)	0.7	6	No
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	No
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	No
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	Yes
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	100.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0	0.1	6	Yes
CareStart™ Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161[m]/G0161-ET	Access Bio, Inc.	90.8	94.1	100.0	100.0	0.3	0.0	1.0	1.5	0.0	0.0	4	Yes[m]
CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171/G0171-ET	Access Bio, Inc.	89.8	91.2	100.0	100.0	0.3	0.7	0.5	2.9	0.0	0.0	4	Yes
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	No
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	78.0	82.9	98.0	100.0	2.8 (399)	0.0 (138)	1.0	0.0	0.0 (207)	0.5	6	Yes
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	100.0	100.0	1.3	1.4	0.0	1.4	3.9	0.0	6	Yes
FalciVax™ - Rapid Test for Malaria Pv/Pf[j]	503010025	Zephyr Biomedicals	80.0	100.0	99.0	100.0	0.5	0.0	0.5	0.0	1.4	0.0	6	Yes
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	85.0	71.4	100.0	100.0	0.0	0.0	0.0 (199)	0.0	0.5 (207)	0.2	6	No
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	Yes
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	Yes
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	Yes
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis, Co., Ltd.	88.0	91.4	100.0	100.0	0.3	0.7	0.0	0.0	1.0 (207)	0.1	6	Yes
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	91.0	48.6	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0	6	No
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	No
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	No
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	No
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	No
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	90.0	51.4	100.0	97.1	0.0 (395)	0.0 (137)	0.5 (198)	0.0	0.0 (203)	1.3	6	No
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	5	No
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	76.0	25.7	100.0	100.0	2.0	0.7	4.0	0.0	1.0	0.0	6	No
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	5	No
One Step Malaria P.f/P.v Whole Blood Test[j]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	78.0	0.0	99.0	74.3	0.0 (399)	0.0	5.5	0.0	0.0	0.1	6	No
OnSite Malaria Pf/Pv Ag Rapid Test[j]	R0112C	CTK Biotech, Inc.	74.0	80.0	98.0	100.0	0.0 (399)	1.4	0.0	0.0	0.0 (207)	0.2	6	No
ParaHIT®fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device	55IC402-50	ARKRAY Healthcare Pvt. Ltd.[n]	63.0	37.1	91.0	85.7	2.0 (399)	5.7	0.5	2.9	6.4	0.1	5	No
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	78.0	25.7	100.0	100.0	4.0	0.0	4.0	0.0	0.0	0.1	6	No
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	Yes
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	100.0	100.0	2.5 (399)	0.0	1.0	2.9	4.4 (207)	0.2	6	Yes
SD Bioline Malaria Ag P.f/P.v[j]	05FK80	Standard Diagnostics, Inc.	92.0	94.3	100.0	100.0	0.5	0.7	0.0	0.0	1.9	0.0	6	Yes[m]
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	No

Table S2 *(continued)*

Product	Product code	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	Meets WHO procurement criteria
							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, Pf and Pv														
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	85.0	91.4	100.0	100.0	0.0	0.0	0.5	0.0	0.0	0.0	6	Yes
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	No
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	No
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	5	Yes
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0.0	99	55.9	NA	NA	NA	NA	2.2	0.2	4	No
CareStart™ Malaria pLDH (PAN)	G0111	Access Bio, Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0	5	Yes[m]
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	No
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	17.2	62.9	90.9	100.0	NA	NA	NA	NA	0.5	0.2	3	No

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; Round 6, n=100

[d] Round 1, n=20; Round 2, n=40; Round 3, n=35; Round 4, n=34; Round 5, n=35; Round 6, 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); Round 6, 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; Round 6, 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; Round 6, 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; Round 6, n=70)

[i] Round 1, n=168; Round 2, n=200; Round 3, n=200; Round 4, n=232; Round 5, n=236; Round 6, n=208

[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 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 ; Round 6, n=1210

[m] Indicates a WHO prequalified product

[n] Span Diagnostics Ltd. is now ARKRAY Healthcare Pvt. Ltd.

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 3–6 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at 35 °C and 45 °C

Product	Product code	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	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
BIONOTE MALARIA P.f. Ag Rapid Test Kit[a]	RG19-11	Bionote,Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
CareStart™ Malaria HRP2 (Pf)	G0141[m]/G0141-ET	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[a]	G0181[m]/G0181-ET	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
First Response® Malaria Ag *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
ICT Diagnostics Malaria P.f.	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	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
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
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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)	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
One Step Malaria P.f Whole blood Test[a]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	93.3	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
OnSite Malaria Pf Ag Rapid Test[a]	R0114C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
Paracheck® Pf-Rapid Test for *P. falciparum* Malaria Device (Ver.3)	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)	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 Ver. 1 (Device)	55IC104-50	ARKRAY Healthcare Pvt. Ltd.[c]	100.0	96.7	100.0	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	3
ParaHIT® - f Ver. 1 (Dipstick)	55IC103-50	ARKRAY Healthcare Pvt. Ltd.[c]	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	3
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)[a, b]	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	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
Pf and pan															
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	4
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	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
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
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	100.0	100.0	100.0	100.0	100.0	100.0	0.0	16.7	0.0	100.0	100.0	100.0	6
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
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit[a]	RG19-08	Bionote, 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	6

Table S3 *(continued)*

Product	Product code	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			
BioTracer™ Malaria P.f/PAN Rapid Card[a]	17012	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.3	66.7	100.0	100.0	100.0	6
CareStart™ Malaria/Pregnancy Combo (pLDH/HRP2/HCG)	G0221	Access Bio Inc	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	3
CareStart™ Malaria HRP2/pLDH (Pf/PAN) COMBO	G0131[m]/G0131-ET	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
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	26.7	80.0	83.3	100.0	100.0	100.0	4
diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	SSA Diagnostics & Biotech Systems	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	90.0	90.0	3
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 Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	3.3	23.3	10.0	100.0	100.0	100.0	6
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	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
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	70.0	100.0	100.0	100.0	6
FirstSign™ ParaView (Pan+Pf)	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
Humasis Malaria P.f/Pan Antigen Test[a]	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
Humasis Malaria P.f/Pan Antigen Test	ANMAL-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	6
ICT Malaria Dual Test	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
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
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	100.0	100.0	96.7	100.0	100.0	100.0	93.1	96.6	36.7	100.0	100.0	90.0	6
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	MFV-124R	AZOG, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	3
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	100.0	96.7	96.7	100.0	100.0	100.0	16.6	0.0	0.0	90.0	40.0	50.0	4
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	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	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
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
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	46.7	56.7	0.0	100.0	100.0	100.0	6
NanoSign Malaria pf/pan Ag 3.0	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	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
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	90.0	100.0	70.0	6
OnSite Malaria Pf/Pan Ag Rapid Test[a]	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	6
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
Parascreen® - Rapid test for Malaria Pan/Pf[a]	503030025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	93.3	100.0	100.0	100.0	6
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	100.0	100.0	100.0	6
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)[a]	C30RHA25	RapiGEN Inc.	100.0	100.0	96.7	100.0	100.0	100.0	0.0	10.0	26.7	100.0	100.0	100.0	6
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

(continued)

Table S3: Malaria RDT rounds 3–6 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at 35 °C and 45 °C *(continued)*

Product	Product code	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/Pan	05FK60	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	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
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 (Pf/Pv) Tri-Line Test (whole blood)[a]	ITP11003 TC40	InTec Products, Inc.	96.7	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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.&t 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
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
CareStart Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161[m]/G0161-ET	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	G0171/G0171-ET	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
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
FalciVax™ - Rapid Test for Malaria Pv/Pf[a]	503010025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	100.0	100.0	96.6	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
One Step Malaria P.F/P.V Test (Cassette)	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
One Step Malaria P.f/P.v Whole Blood Test[a]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
OnSite Malaria 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	6
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
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD Bioline Malaria Ag P.f/P.v[a]	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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
Pf, Pf and Pv															
SD Bioline Malaria Ag P.f/P.f/P.v[b]	05FK120	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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

Table S3 *(continued)*

Product	Product code	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			
Pan only															
Advantage Pan Malaria Card	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)	G0111	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5
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
Parabank™ Device - Rapid test for Malaria Pan	50301025	Zephyr Biomedical Systems	NA	NA	NA	NA	NA	NA	0.0	0.0	0.0	90.0	100.0	100.0	3

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:

[c] Span Diagnostics Ltd. is now ARKRAY Healthcare Pvt. Ltd.

Product	Product code	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/P.f/P.v - (PF(HRP2) line)	05FK120	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD Bioline Malaria Ag P.f/P.f/P.v - (PF(pLDH) line)	05FK120	Standard Diagnostics, Inc.	30.0	30.0	30.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)- (PF(pLDH) line)	05FK90	Standard Diagnostics, Inc.	93.3	90.0	66.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
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

Table S4: Products evaluated during rounds 1–6 that have been removed from summary results listings

Manufacturer	Product	Product code
Amgenix International, Inc.	OnSight™ - Malaria Pf Test	511-25-DB
	OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB
	OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB
	OnSight™ - ParaQuick (Pan, Pf) Test	536-25-DB
Abon Biopharm (Hangzhou) Co. Ltd. (Iverness Medical)	ABON Malaria Pan/P.f.Rapid Test Device (whole blood)	IMA-B402
Access Bio Ethiopia	ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161
	ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171
ACON Biotech (Hangzhou) Co. Ltd	Surestep™ Malaria Pf/Pan Rapid Test Device (Whole Blood)	IMA-T402
Acon Laboratories, Inc	Malaria *Plasmodium* falciparum Rapid Test Device (Whole Blood)	IMA-402
Bhat Bio-Tech India (P) Ltd	Maleriscan® Malaria Pf/Pv	MAT-50
Biosynex	Immunoquick Malaria +4	0506_K25
Diagnostics Automation/Cortez Diagnostics Inc.	Malaria P.F/Vivax	172110P-25
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Card	HR2823
	HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923
	HiSens Malaria Ag Pf HRP2 Card	HR3023
Human GmbH	Hexagon Malaria	58051
	Hexagon Malaria Combi	58024
ICT INTERNATIONAL	ICT Malaria Combo	ML02
	ICT MALARIA P.F.	ML04
IND Diagnostic Inc.	One Step Malaria Antigen Strip	820-1
	IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10
	IND ONE STEP MALARIA ANTIGEN P.f	535-11
Innovatek Medical Inc.	Quickstick Malaria Antigen Test	
Inverness Medical Innovations, Inc.	Binax Now Malaria	IN660050
Medical Diagnostech (Pty) Ltd	MD Malaria Pf/Pan (pLDH) test	MDMALLDH001
Medisensor, Inc.	Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161
	Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171
Orgenics Ltd. (Inverness Innovations)	Clearview® Malaria pLDH	70884025
Orgenics Ltd.(IS)	Clearview® Malaria Dual	VB20
Premier Medical Corporation Ltd.	First Response® Malaria Ag pLDH	I12FRC30
RapiGen inc.	BIOCREDIT Malaria pf(HRP II)	HR0100
Span Diagnostics	ParaHIT®-f Dipstick	55IC101-50/25977
	ParaHIT®- f Device	55IC102-50/25975
	ParaHIT - Total (Device)	55IC202-10/25989
	ParaHIT Pan M (dipstick)	55IC301-10
	ParaHIT total (dipstick)	55IC201-10/25988
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf) Cassette	KMFC6001
	diagnosticks- Malaria (Pf) Dipstick	KMFD6007
	diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100
	SD BIOLINE Malaria Ag Pv	05FK70
	SD BIOLINE Malaria Ag P.f/Pan	05FK63[a]
	SD Bioline Malaria Ag P.f/P.v	05FK83[b]
	SD BIOLINE Malaria Ag Pf	05FK53[c]
Unimed International	FirstSign – Malaria Pf Card Test	-
	FirstSign – ParaView-2 (Pv + Pf) Card Test	2102CB-25
	FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25
	FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25
Vision Biotech (Pty) Ltd	Vision Malaria Pf	VB01
	Clearview® Malaria Combo	VB11
Zephyr Biomedicals	Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025

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

[a] Previously co-listed with 05FK60 (multi-use pack), but removed because single pack format (05FK63) not evaluated at CDC
[b] Previously co-listed with 05FK80 (multi-use pack), but removed because single pack format (05FK83) not evaluated at CDC
[c] Previously co-listed with 05FK50 (multi-use pack), but removed because single pack format (05FK53) not evaluated at CDC

2. EXECUTIVE SUMMARY

2.1. Introduction

WHO estimates that 3.2 billion people are at risk for malaria. In 2014, there were an estimated 214 million cases (with an uncertainty range of 149 million to 303 million) and an estimated 438 000 deaths (with an uncertainty range of 236 000 to 635 000). Approximately 90% of all malaria deaths occur in sub-Saharan Africa, and nearly 70% occur in children under 5 years. Malaria remains endemic in 97 countries, and, while parasite-based diagnosis is increasing, approximately 35% of suspected malaria cases in Africa were not confirmed with a diagnostic test during 2014, 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 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 manufacture. The results of WHO malaria RDT product testing form the basis for procurement criteria and constitute the laboratory evaluation component of WHO prequalification for malaria RDTs. This report provides the results of round 6 of product testing, performed at the CDC during 2014–2015, with data on the performance of 41 products. This round adds to the evaluations of rounds 1–5 (*3*–*7*), 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.

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 tests for evaluation in the programme. The 41 products from 22 manufacturers 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. Observed anomalies were recorded. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a rudimentary assessment of ease of use was recorded. As in previous rounds, RDTs are grouped in the tables and figures into those designed to detect *P. falciparum* only, various combination tests and those that have a line only for pan-specific (or *P. vivax*-specific) malaria. Manufacturers submitted two lots of each product for evaluation. The 16 products that had been tested in previous rounds comprised two compulsory resubmissions and 14 voluntary resubmissions (Tables 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 process for selecting the panel is adjusted to ensure that there is no statistically significant difference in mean or median concentrations of HRP2, aldolase and pLDH antigens 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 seventh round of product testing began in November 2015, and the results will be published in 2017.

Compulsory resubmission was introduced in round 5. Manufacturers who do not submit products that are due for resubmission (every five years) are removed from the summary results (Tables S2 and S3) and the online interactive database, and are only featured in the full round-specific product testing report. These products will not be eligible for WHO procurement. A product is also delisted if WHO is notified by the manufacturer that its production has been discontinued.

2.3. Results of the evaluation

The results (summarized in Tables 4 and 5 and Figs 9, 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 to reliably identify clinical malaria in many settings (*10*), 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 varied, although much less variation was seen for *P. falciparum*-only detecting RDTs in round 6. Generally, products with high performance in detecting parasites have low false-positive rates, good thermal stability and low rates of anomalies. 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.

The basis for *P. falciparum* detection by combination RDTs (*P. falciparum*/pan, *P. falciparum*/*P. vivax*, *P. falciparum*/*P. vivax*, *ovale* and *malariae or P. falciparum*/*P. falciparum*/*P. vivax*), particularly in samples with low parasite density, is predominantly detection of HRP2 and not pLDH. In other words, it is mainly the HRP2 test band that 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). Therefore, when using HRP2 and pan-pLDH (or Pf-pLDH) combination products in the field, it is important to remember that the presence of an HRP2 band combined with the absence of a pLDH band may reflect the lower sensitivity of the pLDH-detecting band in low-density samples and not persistent antigenaemia or successful treatment.

In round 6, the results for both of the retested products were within 7% of the initial test for detection of *P. falciparum* and *P. vivax* at 200 parasites/µL. Most of the differences detected were decreases in PDS performance and improvements in false-positivity rates, in comparison with previous testing. Among the voluntary resubmissions, 29% (4/14) and 60% (6/10) of products showed the same or better detection of *P. falciparum* and *P. vivax* at 200 parasites/µL, respectively. However, detection of *P. falciparum* decreased by 6% on average, while the mean improvement in *P. vivax* detection was 9%. In combination tests, there was no significant correlation between the change in *P. falciparum* and *P. vivax* detection ($p = 0.7$), suggesting that changes in detection of these two parasite species occurred independently.

In round 6, no products had very high false-positive rates when tested against clean negatives, which was an improvement on the high rates observed in rounds 4 and 5. Similarly, while some products did react against blood samples containing specific immunological abnormalities (and against samples containing non-*Plasmodium* infectious agents), these false-positive rates were much lower than that seen in round 5 (Tables A4.6–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.

There was no notable lot variation in round-6 products (Table A4.1); however, as previous rounds have shown variation in performance between the two lots evaluated, it is still recommended that products be lot-tested before field use.

The majority of products showed good heat (thermal) stability on the *P. falciparum* HRP2 test lines after 2 months' storage at 45 °C and 75% humidity. However, Pf-pLDH test lines showed variable baseline performance and deterioration after incubation at 45 °C. For many products, pan-pLDH performance at baseline and post-heat stress for detection of the *P. falciparum* isolate was poor, and it was nearly universally poor against low-parasite-density samples, making it difficult to assess true stability. This round included the first heat stability assessment against a wild-type *P. vivax* sample. While some products performed well, with high positivity after 2 months' storage at 45 °C and 75% humidity, others performed poorly at baseline when detecting pan-pLDH and *P. vivax* pLDH, so that it was difficult to evaluate true stability after incubation. Overall, the pan-pLDH line was more heat stable than the *P. vivax* pLDH line when tested against the *P. vivax* sample.

All products showed at least one anomaly, with some having up to six different types of anomaly that could interfere with test interpretation. The frequency of each anomaly was recorded for the first time in round 6. Incomplete clearing and a red background were the most commonly observed anomalies, seen in 95% and 85% of products, respectively (Table 8). Cases of failed migration, incomplete migration and patchy broken test lines were reported the next most regularly, in 34%, 32% and 37% of products, respectively. Overall, approximately half the products had a frequency of anomalies > 2% (Fig. 30).

The clinical sensitivity of an RDT, i.e. the proportion of known cases of the disease with a positive test, is highly dependent on local conditions, including the parasite density in the target population; it therefore varies in populations with different levels of transmission. The comparative performance between RDTs shown in this report give an indication of which products are likely to be more sensitive in the field, particularly for populations with low-density infections. In general, as the malaria prevalence in countries falls and they even move towards malaria elimination, detection of low parasite densities will become 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, people 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 in this report for HRP2-detecting tests 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 Tables 6a and 6b) is vital to maintaining the sensitivity of a test in the field. For procurement, therefore, the stability results 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 the results in Tables S2, S3 and 5 are colour-coded to reflect achievement of these requirements, as well as WHO prequalification status (indicated in Table S2). A web-based tool maintained by FIND 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 (*13*). This online database has been updated to allow filtering of results by RDT procedural characteristics, such as blood volume requirements, number of buffer drops and time to result. This grouping, also indicated in Annex 1, will allow use of the same or similar protocols to identify products, so that, when product replacement is required, another product with the same or similar protocol may be selected. Use of similar products may reduce the need for user retraining and also reduce user error.

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* spp., target antigen, parasite density, climate) and other important considerations, including ease of use in the field and lot testing. RDTs must not be procured without preparation for proper use, including supply chain management and training in test use and disposal and 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* (*14*) and guidance on implementation in *Universal access to malaria diagnosis* (*15*).

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 (*10*); however, 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).

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 (*16–24*). 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 (*10*).

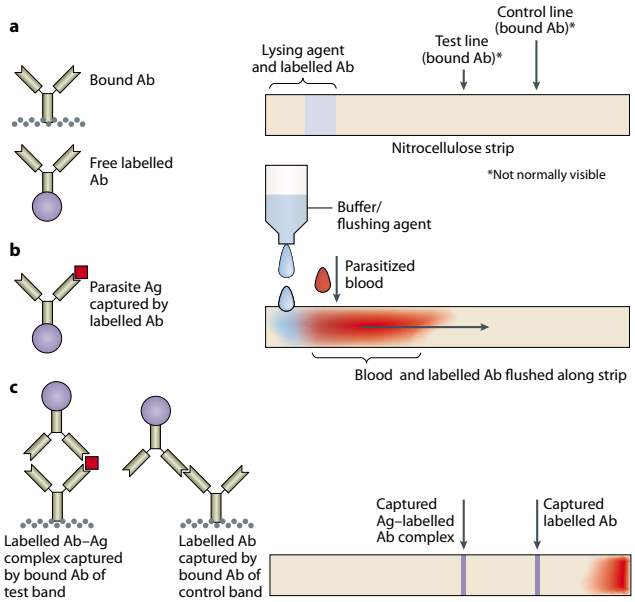
The number of RDTs available on the market has grown rapidly since their introduction in the late 1990s; on the basis of sales reported by 44 manufacturers, 314 million tests were sold in 2014 (*1*). Regulatory control of diagnostics is, however, often weak, and procurement agencies have had considerable 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 in 2002 to evaluate RDTs for malaria, in order 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 (*25, 26*). 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 five rounds of product testing have been released annually since 2009 (*3–7*). This sixth report adds data on the performance of 25 new products and updated data on 16 resubmitted RDTs. Testing for round 6 was conducted against an evaluation panel with characteristics similar to those of 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 30 of 100 *P. falciparum*, 5 of 35 *P. vivax* and 15 of 100 negative samples replaced (new) in round 6.

4. OBJECTIVE

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

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



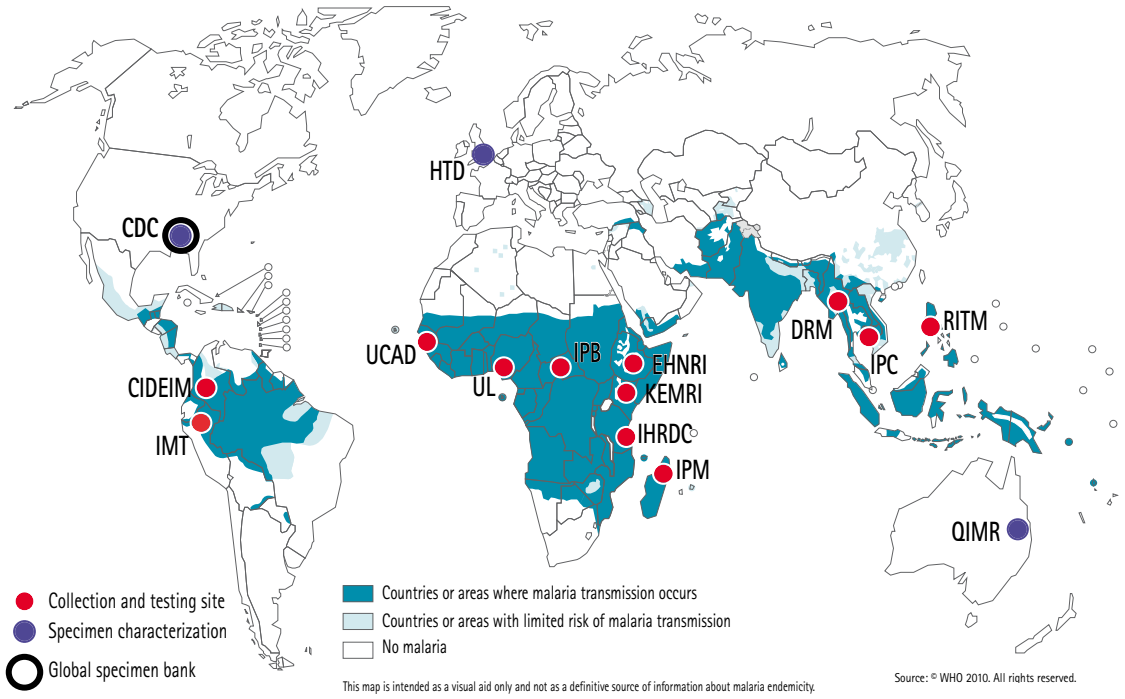
Mode of action of common malaria RDT format:

(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.

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).

5. MATERIALS AND METHODS

5.1. Test selection

In January 2014, 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 6 and the conditions for participation in the evaluation programme (*27*). Manufacturers of products that had not been retested since round 2 were informed they must resubmit these products; otherwise, the performance characteristics would be removed from the summary results document, which is a compilation of the results of all previous rounds of testing. This rule was introduced in round 5 to ensure that all products were retested < 5 years after the primary submission. Other standard requirements included valid ISO 13485:2003 certification of all manufacturing sites, sufficient quantities of products (1100 tests from each of two lots[1]), compliance with the product definition[2] and deadlines for document submission.

Twenty-seven manufacturers, proposing 53 products, responded to the call. Finally, 41 products from 22 manufacturers were tested in round 6 (Table 1a). Catalogue numbers and verification with manufacturers showed that 16 of the 41 products (39%) had been submitted previously to one or more rounds, including two (5%) scheduled for compulsory resubmission (Table 1b). All the products met the minimum

[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://www.who.int/malaria/news/2015/EOI-letter-to-manufacturers-Rd7-annex-2jul2015.pdf?ua=1accessed 9 November 2015*).

Table 1a: Manufacturers and products accepted into round 6 of WHO malaria RDT product testing programme

Manufacturer	Product name	Product code[a]	Target antigen(s)
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf)[b]	G0181/G0181-ET	F(pLDH)/ HRP2
Advy Chemical Private Limited	EzDx™ Malaria Pan/Pf Rapid test detection kit[c]	RK MAL 001	pan(pLDH), HRP2
	EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	V(pLDH), HRP2
	EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	HRP2
Atomo Diagnostics PTY Limited	ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	HRP2, pan(pLDH)
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f/PAN Rapid Card[c]	17012	pan(pLDH), HRP2
	BioTracer™ Malaria P.f/P.v Rapid Card	17412	V(pLDH), HRP2
BioNote, Inc.	BIONOTE MALARIA P.f. Ag Rapid Test Kit[c]	RG19-11	HRP2
	BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit[c]	RG19-08	pan(pLDH), HRP2
Core Technology Co., Ltd.	Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	V(pLDH), HRP2
CTK Biotech, Inc.	OnSite Malaria Pf/Pv Ag Rapid Test[c]	R0112C	HRP2, V(pLDH)
	OnSite Malaria Pf/Pan Ag Rapid Test[c]	R0113C	HRP2, pan(pLDH)
	OnSite Malaria Pf Ag Rapid Test[c]	R0114C	HRP2
Guangzhou Wondfo Biotech Co., Ltd.	One Step Malaria P.f Whole blood Test[c]	W37-C	HRP2
	One Step Malaria P.f/P.v Whole Blood Test[c]	W056-C	V(pLDH), HRP2
	One Step Malaria P.f/Pan Whole Blood Test	W62-C	pan(pLDH), HRP2
Hangzhou Biotest Biotech Co., Ltd.	RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	HRP2
Hema Diagnostic Systems	Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	HRP2
Humasis Co., Ltd.	Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	pan(pLDH), HRP2
	Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	V(pLDH), HRP2
	Humasis Malaria P.f Antigen Test	ANMPF-7025	HRP2
InTec Products, Inc.	Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)[c]	ITP11003 TC40	V(pLDH), HRP2
Lumiquick Diagnostics, Inc.	QuickProfile™ Malaria Pf/Pv Test	71050	V(pLDH), HRP2
	QuickProfile™ Malaria Pf/Pan Test	71063	pan(pLDH), HRP2
Medsource Ozone Biomedicals Pvt. Ltd.	Is It... Malaria Pf/Pv Device	AL030	pan(pLDH), HRP2

Table 1a: *(continued)*

Manufacturer	Product name	Product code[a]	Target antigen(s)
Meril Diagnostics Private Ltd.	Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	pan(pLDH), HRP2
	Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	V(pLDH), HRP2
Nantong Egens Biotechnology Co., Ltd.	Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	V(pLDH), HRP2
Oscar Medicare Pvt. Ltd.	Malaria Antigen Test-Pf	MAG01040	HRP2
Premier Medical Corporation Ltd.	First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	HRP2
	First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	pan(pLDH), HRP2
	First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	V(pLDH), HRP2
RapiGEN Inc.	RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	HRP2
	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	V(pLDH), HRP2
	RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)[c]	C30RHA25	pan(pLDH), HRP2
Shanghai Kehua Bio-engineering Co., Ltd.	KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	V(pLDH), HRP2
Standard Diagnostics, Inc.	SD Bioline Malaria Ag P.f/P.v[b]	05FK80	V(pLDH), HRP2
	SD Bioline Malaria Ag P.f (HRP2/pLDH)[c]	05FK90	F(pLDH), HRP2
	SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	V(pLDH),F(pLDH), HRP2
Zephyr Biomedicals	FalciVax™ - Rapid Test for Malaria Pv/Pf[c]	503010025	V(pLDH), HRP2
	Parascreen® - Rapid Test for Malaria Pan/Pf[c]	503030025	pan(pLDH), HRP2

pLDH, *Plasmodium* lactate dehydrogenase; HRP2, histidine-rich protein 2; V, *P. vivax;* F, *P. falciparum*

[a] The product code corresponds to a specific configuration of the RDT, kit components and accessories. Therefore, changes to this configuration including the quantity of tests, the contents or the manufacturing site are denoted by a different product code. Often this involves the end portion of the product code; however, the manufacturer should be contacted for full details.

[b] Indicates products submitted for compulsory retesting in round 6

[c] These products have been submitted voluntarily in previous rounds of WHO malaria RDT product testing (round 1-5). For details on all product resubmissions refer to Table S1.

Table 1b: Products due for compulsory resubmission in round 6

Manufacturer	Product	Product Code	Participation in round 6[a]
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH Pf test	G0181	Yes
Amgenix International, Inc.	OnSight™ - Malaria Pf Test	511-25-DB	No
Amgenix International, Inc.	OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB	No
Amgenix International, Inc.	OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB	No
Bhat Bio-Tech India (P) Ltd	Maleriscan® Malaria Pf/Pv	MAT-50	No
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Card	HR2823	No
HBI Co., Ltd.	HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923	No
HBI Co., Ltd.	HiSens Malaria Ag Pf HRP2 Card	HR3023	No
Premier Medical Corporation Ltd.	First Response® Malaria Ag pLDH	I12FRC30	No
Span Diagnostics Ltd	ParaHIT Pan M (dipstick)	55IC301-10	No
Span Diagnostics Ltd	ParaHIT® total (dipstick)	55IC201-10	No
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf) Cassette	KMFC6001	No
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf) Dipstick	KMFD6007	No
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002	No
Standard Diagnostics, Inc.	SD BIOLINE Malaria Ag Pv	05FK70	No
Standard Diagnostics, Inc.	SD BIOLINE Malaria Ag Pf/Pv	05FK80	Yes
Unimed International Inc.	FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25	No
Unimed International Inc.	FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25	No
Zephyr Biomedicals	Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025	No

[a] The results of the first testing of the products in this list that were not retested in round 6 have been removed from Tables S2 and S3 and Figs S1 and S2 and are listed in Table S4.

performance requirements[1] in the initial evaluation against the *P. falciparum* culture-derived panel and were therefore evaluated fully in phase 2.

Of the 41 products that were fully evaluated, 12 are designed to detect *P. falciparum* alone, 13 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria and 16 to differentiate *P. falciparum* from *P. falciparum* and *P. vivax*. Of these products, three detected *P. falciparum* pLDH. Two products had separate Pf-pLDH detecting lines and the third product combined *P. falciparum* pLDH with HRP2 on the same line. 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 6 (*26*). 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. Both lots were also tested for heat (thermal) stability, evaluated after 2 months' storage at room temperature (21–24 °C), 35 °C and 45 °C. An ease-of-use description was completed on a standard assessment format, and common 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.

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[2] parasites/µL), all samples prepared from isolates that express HRP2; and
- a parasite-negative panel ("clean" samples and disease-specific or blood factor-specific samples).

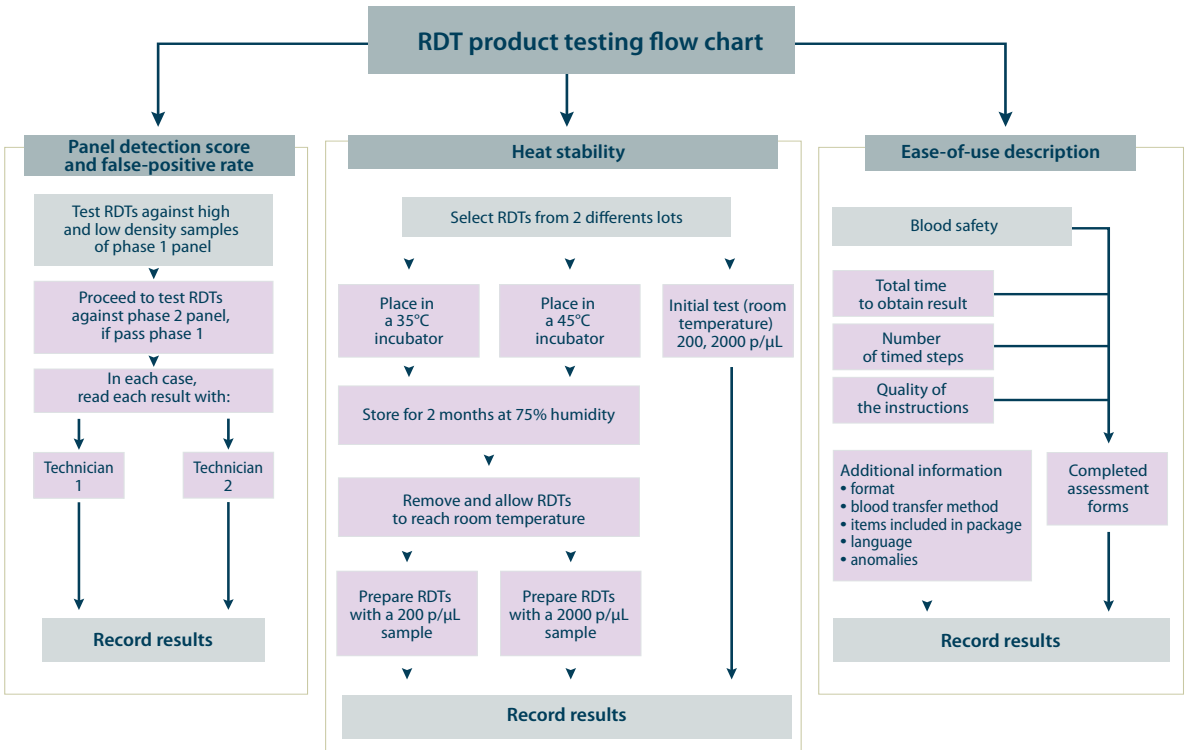
An overview of sample collection and characterization is given in the methods manuals prepared for this purpose (*25, 26*). Characterization results for each round are available on the WHO GMP and FIND websites (*28*). Thus, each panel specimen was characterized for:

- 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.

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

[2] Three (3%) of the 100 *P. falciparum* dilution sample sets contained 200 and 5000 parasites/µL.

Figure 3: Overview of malaria RDT product testing



Most *P. falciparum* samples in the global specimen bank were also characterized according to HRP2 sequence by PCR amplification and sequencing. This was not performed on samples collected after 2009, as accumulated evidence indicates that HRP2 variation has no significant effect on RDT sensitivity (*29*). The geographical origin of all samples was recorded.

Panel composition

P. falciparum-cultured parasites panel

The programme selected culture-adapted strains of *P. falciparum* from various geographical locations, including 13 strains with type B HRP2 sequence, five with type A and two with type C. All specimens were derived from the CDC culture bank and diluted in O-positive blood from donors in the USA (*26*).

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 11 collection sites in Africa, Asia and South America (Figs 2, 4a and 4b). Samples were collected from febrile patients and processed by standard 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. The concentrations of sample antigens (HRP2, pLDH, aldolase) determined by quantitative ELISA are shown in Table 3. The results are based on 98 *P. falciparum* samples for pLDH, 99 *P. falciparum* samples for HRP2 and 100 for aldolase, 34 *P. vivax* samples for pLDH and 35 *P. vivax* samples for aldolase. This panel is closely comparable to those of previous rounds (Annex S1).

Negative blood sample panel

The negative panel consisted of 52 "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 and PCR. The negative sample panel also contained 48 parasite-negative samples from donors with diseases that might be used in the differential diagnoses of malaria, 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 to be free of *Plasmodium* parasites by PCR amplification.

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

Nature of negative sample[a]	No.
Clean-negative[b]	52
Anti-nuclear antibody positive (sera)	13
Anti-mouse antibody positive (plasma)	3
Rheumatoid factor positive (whole blood and sera)	6
Rapid plasma reagin positive (sera)	7
Chagas' disease antibody positive (plasma)	2
Dengue antibody positive (whole blood sera)	6
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)

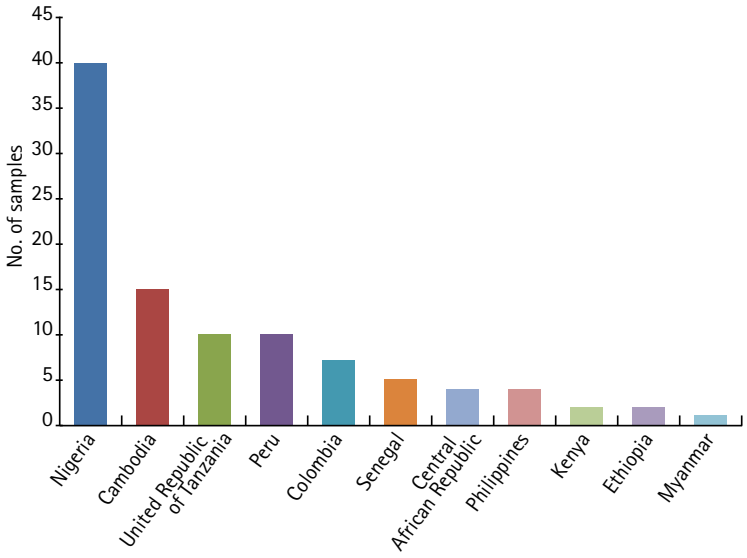


Figure 4b: Origin of phase 2 *P. vivax* wild-type (clinical) samples (n=35)

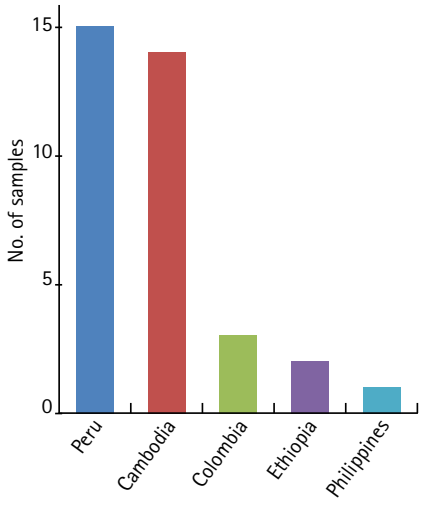


Table 3: Malaria antigen concentrations (ng/mL) in round 6 wild-type, low parasite density (200 parasites/µL) samples

	pLDH		HRP2	Aldolase	
	P. falciparum	*P. vivax*	*P. falciparum*	*P. falciparum*	*P. vivax*
Mean	15.6	16.9	12.2	1.5	7.7
Median	11.8	15.2	8.1	1.2	6.5
Maximum	53.5	44.8	62.5	9.1	15.1
Minimum	0.2	1.6	0.7	0.0	1.7
Standard deviation	12.0	11.8	13.3	1.6	3.7

5.4. Product 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 (21–24 °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 was 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, and against 20 clean negative samples. 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. Round 6 included the first heat stability assessment against a *P. vivax* isolate. Because the number of aliquots were smaller, fewer replicate RDTs were performed.

- 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) parasites/µL[2]) and 100 parasite-negative samples.
- Heat stability evaluation (*P. falciparum*-detecting products): 15 RDTs from each of two lots were tested against a single culture-derived *P. falciparum* isolate (Nigeria XII strain, *P. falciparum* HRP2 sequence type B) with a typical antigen concentration[3] of 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, which were all tested at baseline and after RDTs were maintained for 60 days at room temperature (< 25 °C), 35 °C and 45 °C, at 75% humidity. Evaluation of heat stability for *P. vivax*-detecting products: Four RDTs from each of the two lots were tested against a single wild-type *P. vivax* sample[4] (from Ethiopia) at 200 parasites/µL, two RDTs from each lot against *P. vivax* at 2000 parasites/µL and four RDTs from each lot against a negative sample, at baseline and after RDTs were maintained for 60 days at room temperature (< 25 °C), 35 °C and 45 °C, at 75% humidity. The pLDH concentrations in the samples chosen were above average in order to increase the probability of good RDT baseline reactivity, thereby allowing an interpretable assessment of stability or degradation.
- 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 (*26*).
- RDT anomalies: During testing, technicians regularly reported the RDT anomalies listed below (not all of which were observed in round 6) and in Fig. AS2.1. When anomalies were noted frequently, a photograph was taken of at least one example.
  - red background
  - red background obscuring test line(s)
  - incomplete clearing
  - incomplete migration
  - failed migration
  - ghost test line(s)
  - patchy, broken test line(s)

[1] A sample set typically consists of 13 *P. falciparum* specimens and five *P. vivax* specimens at 200 parasites/µL and 2000 parasites/µL (or 5000 parasites/µL) and 13 malaria-negative samples.

[2] Three (3%) of the 100 *P. falciparum* dilution samples sets were at 200 and 5000 parasites/µL.

[3] The *P. falciparum* sample had18.8ng/mL of HRP2, 21.1ng/mL of pLDH and 0.49ng/mL of aldolase.

[4] The *P. vivax* sample had 143.9ng/mL of pLDH and 44.4ng/mL of aldolase.

- diffuse test line(s)
- strip misplaced in cassette (shift)
- specimen pad not seen in sample window
- buffer remains pooled in buffer well

5.7. Performing rapid tests

All RDTs were maintained at room temperature (21–24 °C) until first use. When applicable, the desiccant was inspected for colour change, and products were discarded if they were present. Technicians were rotated and blinded to the sample type and to each other's results. RDTs were labelled with a sample identification number and the date on which test was performed. The tests were used according to the manufacturer's instructions, except that the recommended volume of blood was transferred by micropipette from the sample tube; 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. Annexes 1 and 2 give a descriptive, illustrated summary of the test characteristics and steps and a guide to interpretation of results.

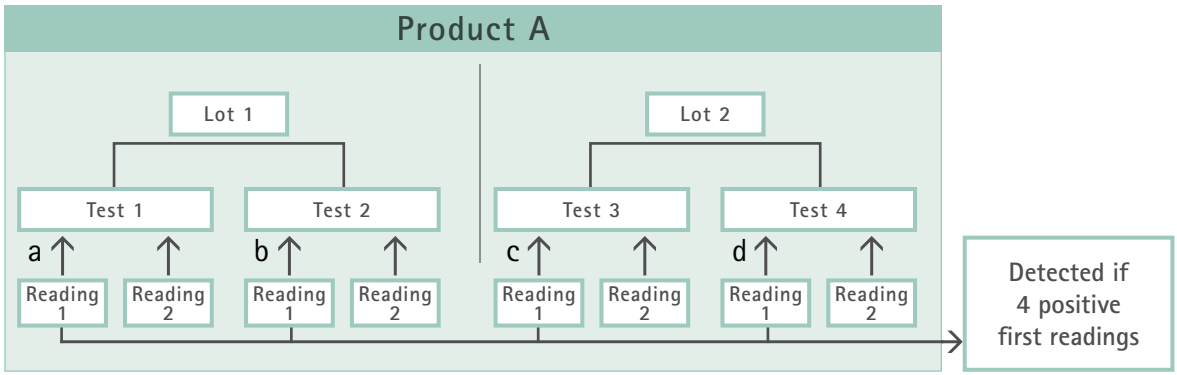
5.8. Interpreting the results

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

Figures 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.

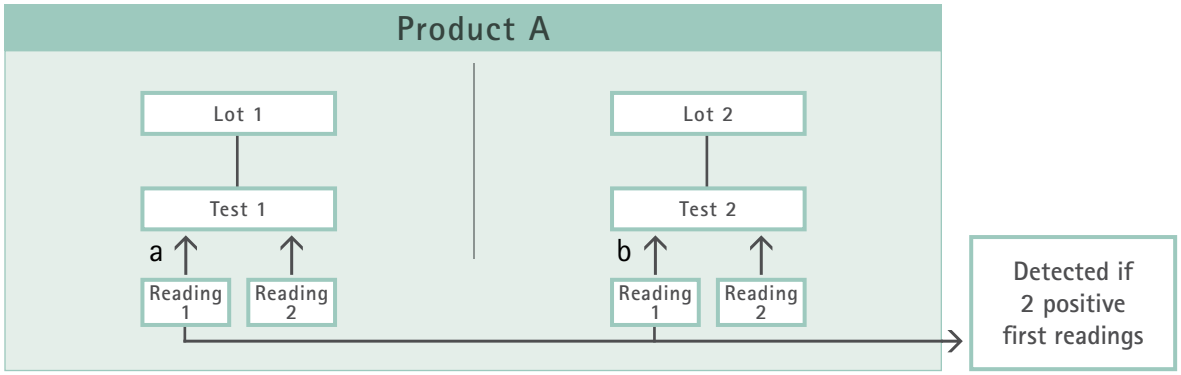


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[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

5.9. Recording anomalies

Anomalies are defined as unexpected features that appear when performing an RDT. Anomalies have been observed since round 1; following the appearance of each, technicians agreed upon terms with which to identify them. During earlier rounds of testing, their presence was informally recorded (and reported to manufacturers), but, in round 6, the frequency of anomalies was recorded. Some anomalies do not interfere with the interpretation of results, while others may obscure test or control lines and therefore affect the interpretation and create confusion. Manufacturers are encouraged to reduce or eliminate anomalies or, at minimum, acknowledge them in their instructions for use.

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 and raw data were sent to manufacturers on 21 September 2015 for a 30-day review period before production of the final report.

7. QUALITY ASSURANCE

Product testing follows standard operating procedures developed during previous testing rounds, which are based on recommendations by expert consultants, with minor modifications by the steering committee before round 6 (*26*). 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 (21–24 °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). Lots were analysed at temperatures above and below the manufacturer's recommended storage conditions.

7.2. Quality and objectivity of RDT readings

The results were read under good lighting by trained technicians tested for visual acuity and were doubly entered into the database. Technicians were rotated, and 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, then exchanged with the second technician, 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 hours 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 for 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 when 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 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 (dengue, leishmania, Chagas, schistosoma and rapid plasma reagin, which is indicative of syphilis infection) and immunological factors (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.

[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.

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 (Pv)	False-positive (non-Pf)	Negative
Pv	False-positive (Pf)	False-positive (Pf)	✚	Negative

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* or one wild-type *P. vivax* parasite sample at 200 and 2000 parasites/µL based on the first reading of two lots at each parasite density (maximum score is 30 (*P. falciparum*) or eight (*P. vivax*) against 200 parasites/µL samples and 10 (*P. falciparum*) or four (*P. vivax*) against 2000 parasites/µL samples)[1] and mean band intensity (for positive tests only based on the first reading) after the lots were stored at room temperature (21–25 °C) and at 35 °C and 45 °C for 2 months.

9.7. Anomalies

The presence and frequency of commonly observed anomalies – red background, red background obscuring test line(s), incomplete clearing, incomplete migration, failed migration, strip misplaced in cassette (shift), specimen pad not seen in the sample window, ghost test line(s), diffuse test line(s), patchy broken line(s) and buffer remains pooled in buffer well – were routinely recorded for all round-6 products. Photographs and descriptions are shown in Fig. AS2.1.

[1] Fifteen tests per lot against 200 parasites/µL samples and five tests per lot against 2000 parasites/µL for *P. falciparum* samples and four tests per lot against 200 parasites/µL samples and two tests per lot against 2000 parasites/µL for *P. vivax* 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 variations 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 HRP2, 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 average antigen levels between the panels for rounds 1–6 were detected for any of the antigens ($p > 0.5$, 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 EVALUATIONS OF RAPID DIAGNOSTIC TESTS

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 because 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 (*11–12*). 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 to 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 the parasite density is very high, no differences in the PDS or positivity rates of tests or much smaller differences will be observed than 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 6 of WHO malaria RDT product testing provided results for 41 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 August 2014 and June 2015, approximately 64 370 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 all species or *P. falciparum* and *P. vivax*. Note that only tests against *P. falciparum* and *P. vivax* were evaluated, and the evaluation therefore does not indicate whether a product intended to detect other species can do so.

PDS values at both high and low parasite concentrations are presented, as are false-positive rates and the percentages 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 (Tables 6a and 6b) 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 *P. falciparum* and negative samples, including *P. falciparum* PDS, *P. falciparum* positivity rate and heat stability, were similar to those in rounds 1–5 (*3–7*), but the false-positivity rates and *P. vivax* PDS and *P. vivax* positivity rates were better than in previous rounds.

  The median PDS for *P. falciparum* was the same as in round 5 (85%), both being slightly lower than in round 4 (89.3%) at low parasite densities. No products in round 6 scored a PDS of 100% for the *P. falciparum* detecting line. The PDS for *P. vivax* at low densities has improved consistently since round 1 (median, 30%), the results for rounds 2, 3, 4, 5 and 6 being 75.0%, 51.4%, 61.8%, 65.7% and 82.9%, respectively. Two products achieved 100% PDS on their pan-pLDH and *P. vivax* pLDH lines when tested against *P. vivax* but had lower scores for their *P. falciparum* detecting lines. The median false-positive rate on clean negative samples and samples containing other infectious agents was 0%, while samples containing immunological factors had an overall false-positive rate of 0.9%.
- 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, increasing the number of available well-performing tests from that in rounds 1–5.
- The performance of products varied at low parasite density (200 parasites/µL), but most showed high detection rates for *P. falciparum* and *P. vivax* at 2000 (or 5000) parasites/µL.
- All round-6 products had an HRP2 detecting line, and most products achieved a high PDS for *P. falciparum* detection.
- Several combination tests achieved PDS at the upper end of the range for both *P. falciparum* and *P. vivax*. (Fig. S3).
- There was little variation in the test performance of lots of round-6 products.
- Approximately half of the combination tests in which HRP2 was used for detection of *P. falciparum* returned positive results only on the HRP2 band at lower densities of *P. falciparum*. Manufacturers' instructions should therefore classify *P. falciparum* 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

Table 4: Summary phase-1 performance of 41 malaria RDTs against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200 parasites/µL	2000 parasites/µL	200 parasites/µL (n=80)	2000 parasites/µL (n=40)	
Pf only							
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	100.0	100.0	NA	NA	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	100.0	100.0	NA	NA	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	65.0	100.0	NA	NA	0.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	100.0	100.0	NA	NA	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	100.0	100.0	NA	NA	0.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	100.0	100.0	NA	NA	0.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	100.0	NA	NA	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	85.0	100.0	NA	NA	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	100.0	100.0	NA	NA	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	100.0	100.0	NA	NA	1.7
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	95.0	100.0	NA	NA	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	100 (100 / 55)[c]	100 (100 / 100)[c]	NA	NA	0.0
Pf and pan							
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	100.0	100.0	0.0	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	100.0	100.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	90.0	100.0	1.3	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	95.0	100.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	100.0	100.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	95.0	100.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	95.0	100.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	95.0	100.0	0.0	0.0	0.0
OnSite Malaria 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	503030025	Zephyr Biomedicals	100.0	100.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	100.0	100.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	100.0	100.0	0.0	0.0	0.0
Pf and Pv							
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	95.0	100.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	100.0	100.0	0.0 (79)	0.0 (39)	1.7
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	85.0	100.0	0.0	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	100.0	100.0	0.0	0.0	0.0
First Response® Malaria Ag *Pf/Pv* Card Test	PI19FRC	Premier Medical Corporation Ltd.	95.0	100.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	95.0	100.0	0.0	0.0	0.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	95.0	100.0	0.0 (79)	0.0	0.8
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	95.0	100.0	0.0	0.0	0.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	90.0	100.0	0.0	0.0	0.0

Table 4: Summary phase-1 performance of 41 malaria RDTs against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite density (parasites/µL) *(continued)*

Product	Product code	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200 parasites/µL	2000 parasites/µL	200 parasites/µL (n=80)	2000 parasites/µL (n=40)	
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	95.0	100.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	95.0	100.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	100.0	100.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	100.0	100.0	0.0	0.0	0.0
Pf and Pf and Pv							
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	100 (100 / 35)[c]	100 (100 / 100)[c]	0.0	0.0	0.0

NA, not applicable

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

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

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

[c] Product PDS shown along with PDS for HRP2 band and Pf-pLDH band, respectively

Table 5: Summary phase-2 performance of 41 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	Product code	Manufacturer	Panel detection score[b]				False-positive rates (%)				Total false-positive rates[e] (%)	Invalid rate (%) (n=1210)
			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)[a]	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=208)	
Pf only												
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.5	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	91.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	71.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.1
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	100.0	NA	NA	1.4	NA	1.4	1.4	0.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	91.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	75.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.2
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	100.0	NA	NA	2.9 (139)	NA	0.0	0.0	0.2
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	99.0	NA	NA	0.7	NA	0.0	0.5 (207)	0.2
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	88 (87 / 52)[f]	NA	100 (100 / 97)[f]	NA	NA	0.7	NA	0.0	0.0	0.0
Pf and pan												
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	90.0	22.9	100.0	97.1	0.0 (399)	2.9	0.0	0.0	0.0 (207)	0.2
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	83.0	68.6	100.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	83.0	100.0	100.0	100.0	4.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	100.0	100.0	0.3	0.0	0.0	0.0	1.4	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	100.0	100.0	1.5	0.0	0.0	0.0	1.9 (207)	0.1
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	89.0	62.9	99.0	97.1	0.0	0.7 (139)	0.0	1.4	0.5	0.1
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	88.0	91.4	99.0	100.0	0.5 (395)	0.0	0.0	0.0 (68)	1.0 (206)	0.8
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	77.0	71.4	100.0	100.0	1.3	0.0	0.0	0.0	0.5	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	77.0	14.3	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	78.0	85.7	99.0	97.1	0.0 (398)	0.0	0.5	1.4	0.0 (207)	0.2
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	79.0	97.1	100.0	100.0	2.3	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	99.0	100.0	6.5	1.4	0.5 (199)	0.0	7.2	0.1
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	90.0	91.4	100.0	94.3	0.0 (399)	0.0	0.0	2.9	2.4 (207)	0.1
Pf and Pv												
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	74.0	48.6	100.0	100.0	0.0 (396)	0.0	0.0 (199)	0.0 (69)	0.0 (207)	0.7
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	100.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0	0.1
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	78.0	82.9	98.0	100.0	2.8 (399)	0.0 (138)	1.0	0.0	0.0 (207)	0.5
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	100.0	100.0	1.3	1.4	0.0	1.4	3.9	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	80.0	100.0	99.0	100.0	0.5	0.0	0.5	0.0	1.4	0.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	85.0	71.4	100.0	100.0	0.0	0.0	0.0 (199)	0.0	0.5 (207)	0.2

Table 5: Summary phase-2 performance of 41 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 *(continued)*

Product	Product code	Manufacturer	Panel detection score[b]				False-positive rates (%)				Total false-positive rates[e] (%)	Invalid rate (%) (n=1210)
			200 parasites/µL		2000 parasites/µL		200 parasites/µL		2000 parasites/µL		Clean-negative samples	
			Pf samples (n=100)	Pv samples (n=35)	Pf samples (n=100)[a]	Pv samples (n=35)	Pf samples	Pv samples	Pf samples	Pv samples		
							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=208)	
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	88.0	91.4	100.0	100.0	0.3	0.7	0.0	0.0	1.0 (207)	0.1
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	91.0	48.6	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	90.0	51.4	100.0	97.1	0.0 (395)	0.0 (137)	0.5 (198)	0.0	0.0 (203)	1.3
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	76.0	25.7	100.0	100.0	2.0	0.7	4.0	0.0	1.0	0.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	78.0	0.0	99.0	74.3	0.0 (399)	0.0	5.5	0.0	0.0	0.1
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	74.0	80.0	98.0	100.0	0.0 (399)	1.4	0.0	0.0	0.0 (207)	0.2
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	78.0	25.7	100.0	100.0	4.0	0.0	4.0	0.0	0.0	0.1
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	100.0	100.0	2.5 (399)	0.0	1.0	2.9	4.4 (207)	0.2
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	92.0	94.3	100.0	100.0	0.5	0.7	0.0	0.0	1.9	0.0
Pf and Pf and Pv												
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	85 (84 / 36)[f]	91.4	100 (100 / 98)[f]	100.0	0.0	0.0	0.5	0.0	0.0	0.0

NA, not applicable

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

[a] 3 (3%) of the 100 *P. falciparum* 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] Positive Pf line indicates a false positive *P. falciparum* infection

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

[f] Product PDS shown along with PDS for HRP2 band and Pf-pLDH band, respectively

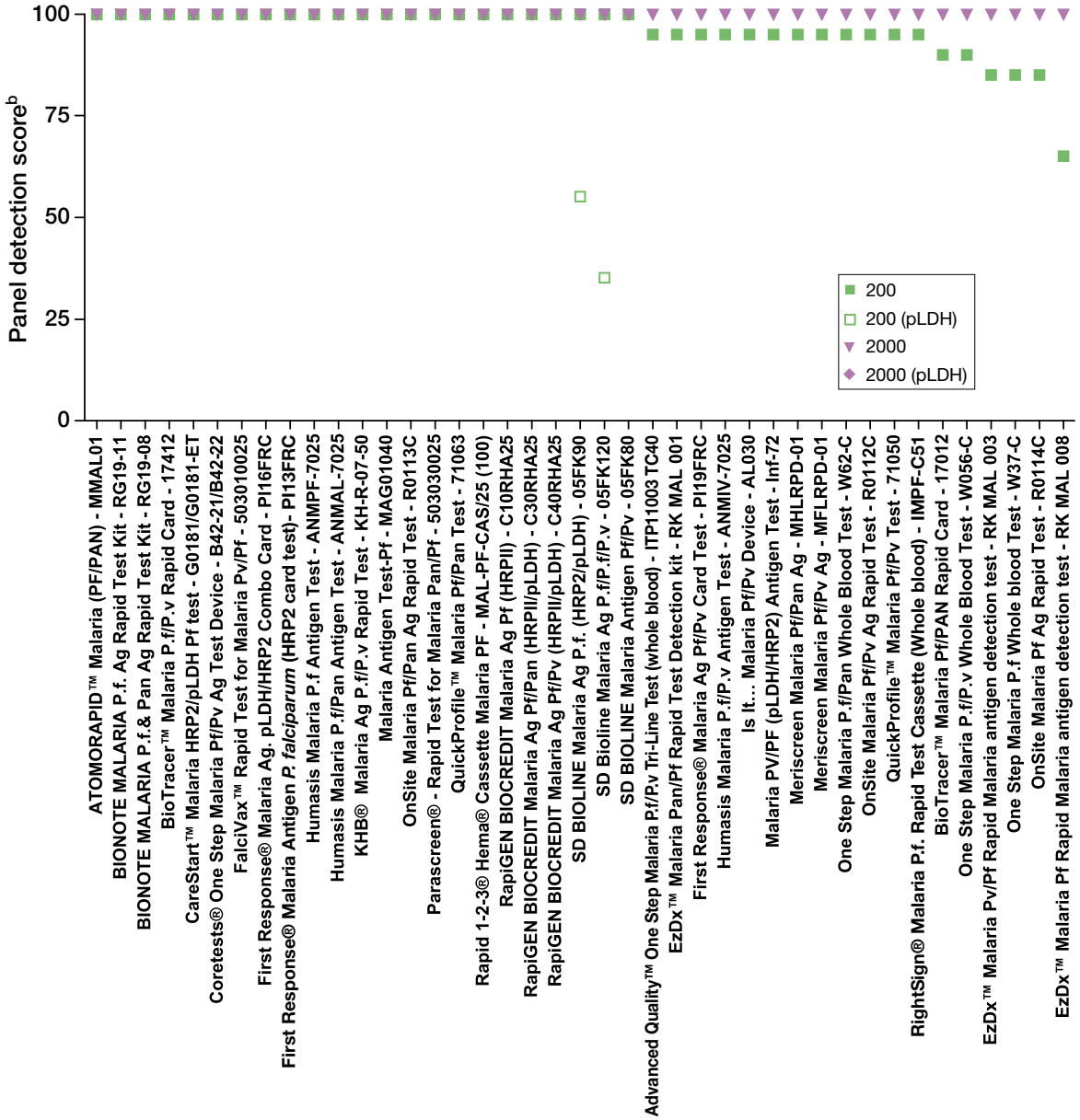
Performance measure	Recommended WHO procurement criteria
Panel detection score for Pf and Pv 200/µL samples	≥ 75%
False-positive rates against clean-negatives	< 10%
Invalid rate	< 5% of tests conducted

of product testing are given in Annexes 3 and 4, respectively. The data are shown graphically in Figs. 9–19.

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

All tests consistently detected 100% of cultured *P. falciparum* parasites at high parasite density (2000 or 5000 parasites/µL); however, the PDS was variable (65–100%) at low parasite density (200 parasites/µL) (Fig. 9).

Figure 9: Phase-1 *P. falciparum* panel detection score of malaria RDTs[a] at low (200) and high (2000) parasite density (parasites/µL)



[a] All RDTs target HRP2 and two products (05FK90 and 05FK120) target both HRP2 and Pf-pLDH. Pf-pLDH based results are presented separately in Table 4.

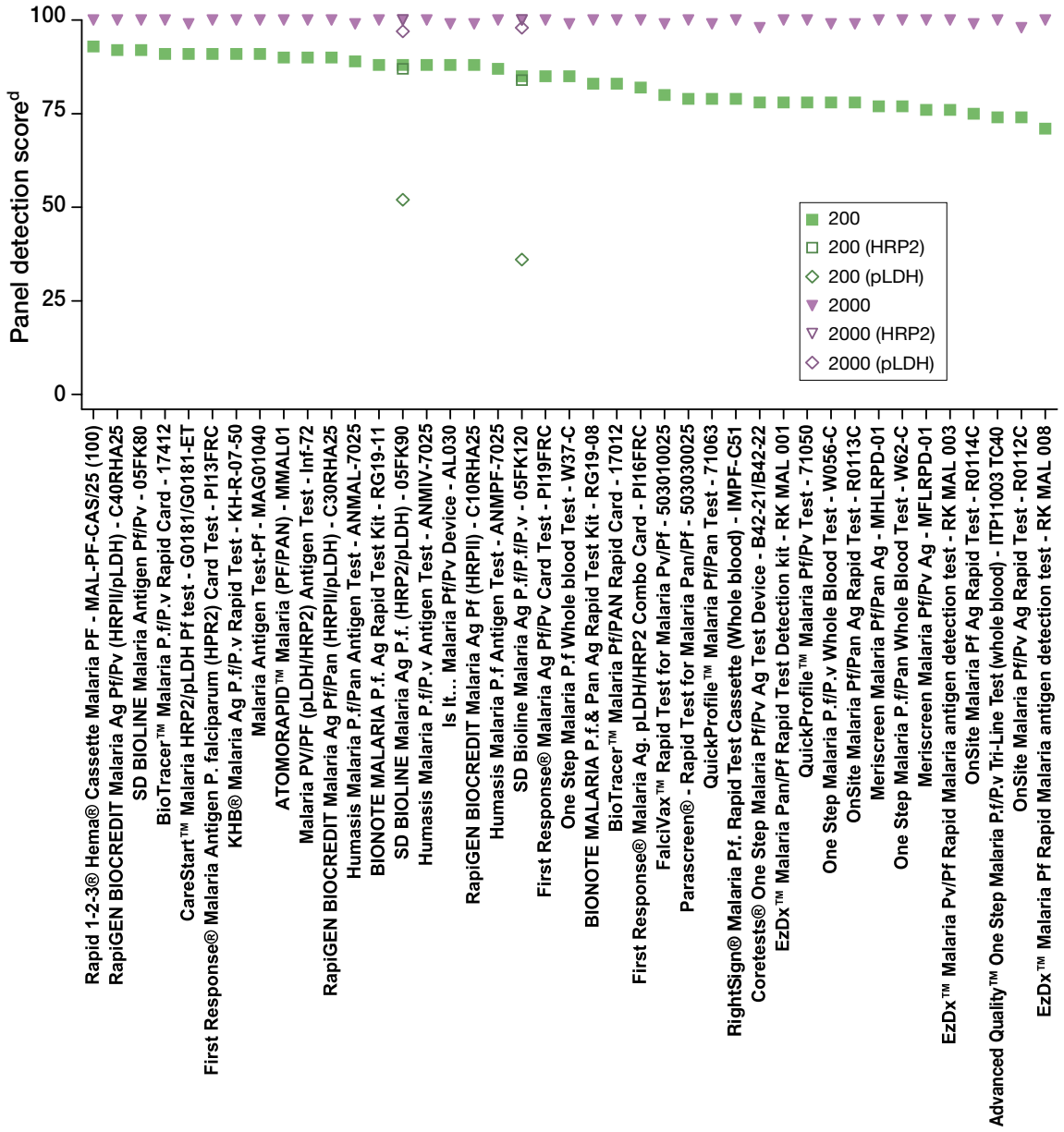
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

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

12.3.1 *P. falciparum* detection

All 41 products in round 6 were designed to detect *P. falciparum*. As in phase 1, all the tests had a PDS ≥ 95% for *P. falciparum* samples at high parasite densitiy. Eleven of the 12 products specific for *P. falciparum* alone achieved a PDS ≥ 75% against samples with low parasite density (Table 5, 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)[b,c]



[a] 3 (3%) of the 100 *P. falciparum* dilution samples sets were 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] All RDTs target HRP2 and two products (05FK90 and 05FK120) target both HRP2 and Pf-pLDH. Pf-pLDH based results are presented separately in Table 5

[d] 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.

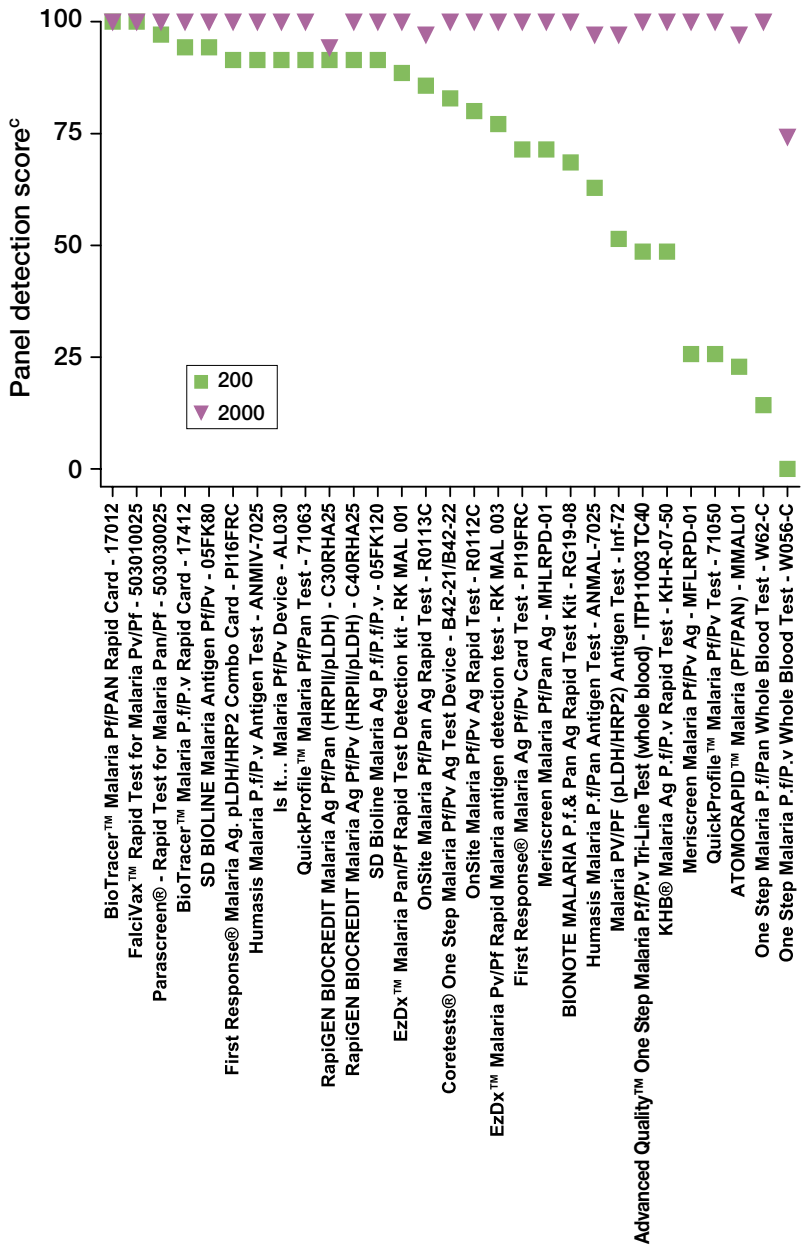
12.3.2 *P. vivax* detection

Fig. 11 shows that 28 of 29 (97%) products designed to detect *P. vivax* consistently detected ≥ 75% at high parasite density (2000 parasites/µL), and 17 (59%) achieved the same threshold of PDS against samples with 200 parasites/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 parasites/µL), 12 products had a PDS ≥ 90%, and 12 had a PDS < 75% (Table 5, Fig.11), which is an improvement on round-5 results in which only eight products had a PDS ≥ 90% and 19 had a PDS < 75%.

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

Of the 29 pan-specific and combination tests, 16 (55%) had a PDS ≥ 75% for both *P. falciparum* and *P. vivax* at a low parasite density (200 parasites/µL) (Table 5). Most products 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) parasite density (parasites/µL)[a,b]



[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] All RDTs target pan-pLDH or Pv-pLDH

[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.

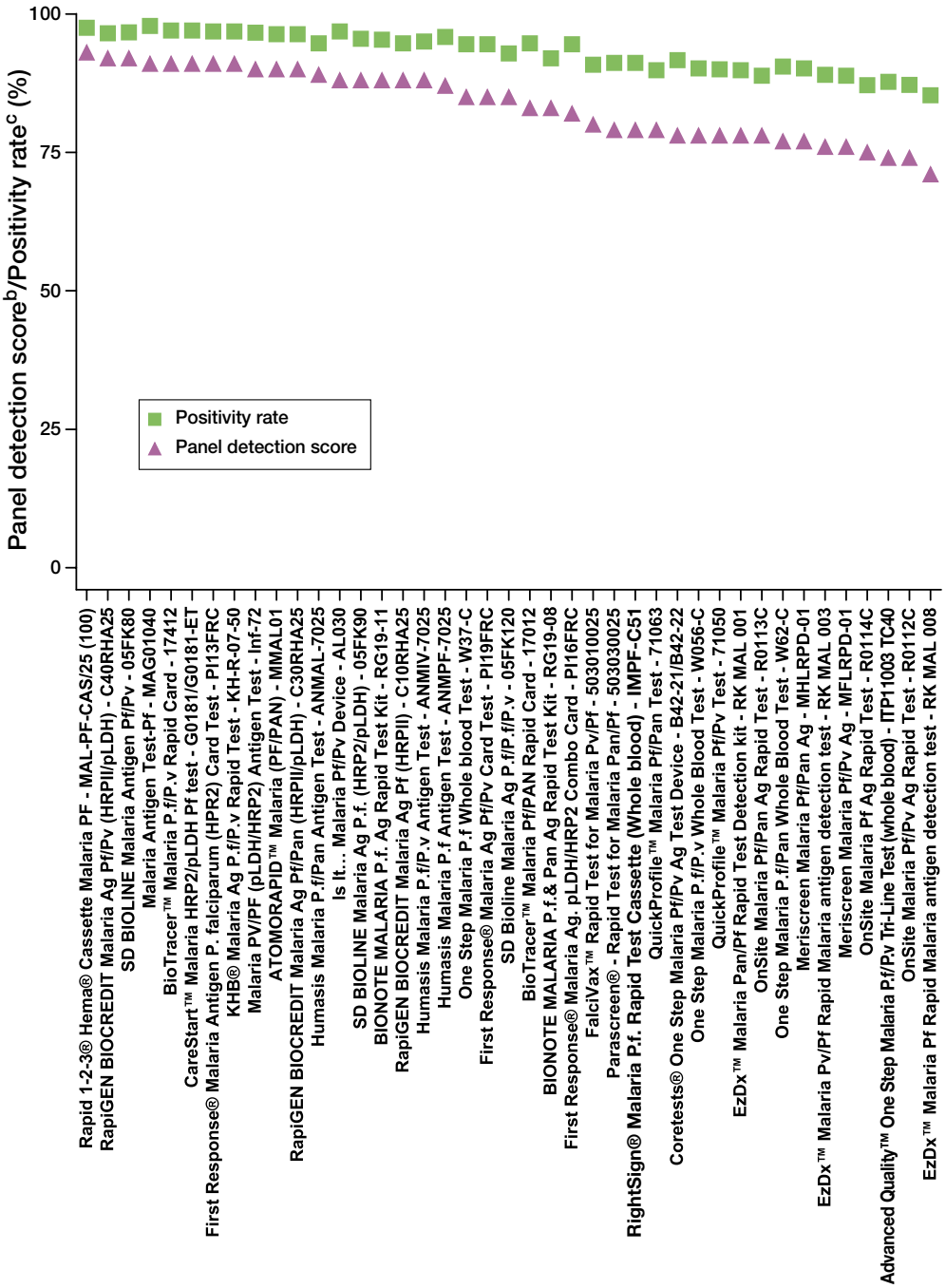
12.3.4 *P. falciparum* and *P. vivax* positivity rate

The positivity rate was calculated 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 A3.2 (for phase 1), A4.2 and A4.3 (for phase 2)). A positive correlation was found between the PDS and band intensity (Spearman rank correlation, $r = 0.80$, $p < 0.001$ for the *P. falciparum* phase-2 panel and $r = 0.90$, $p < 0.001$ 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.

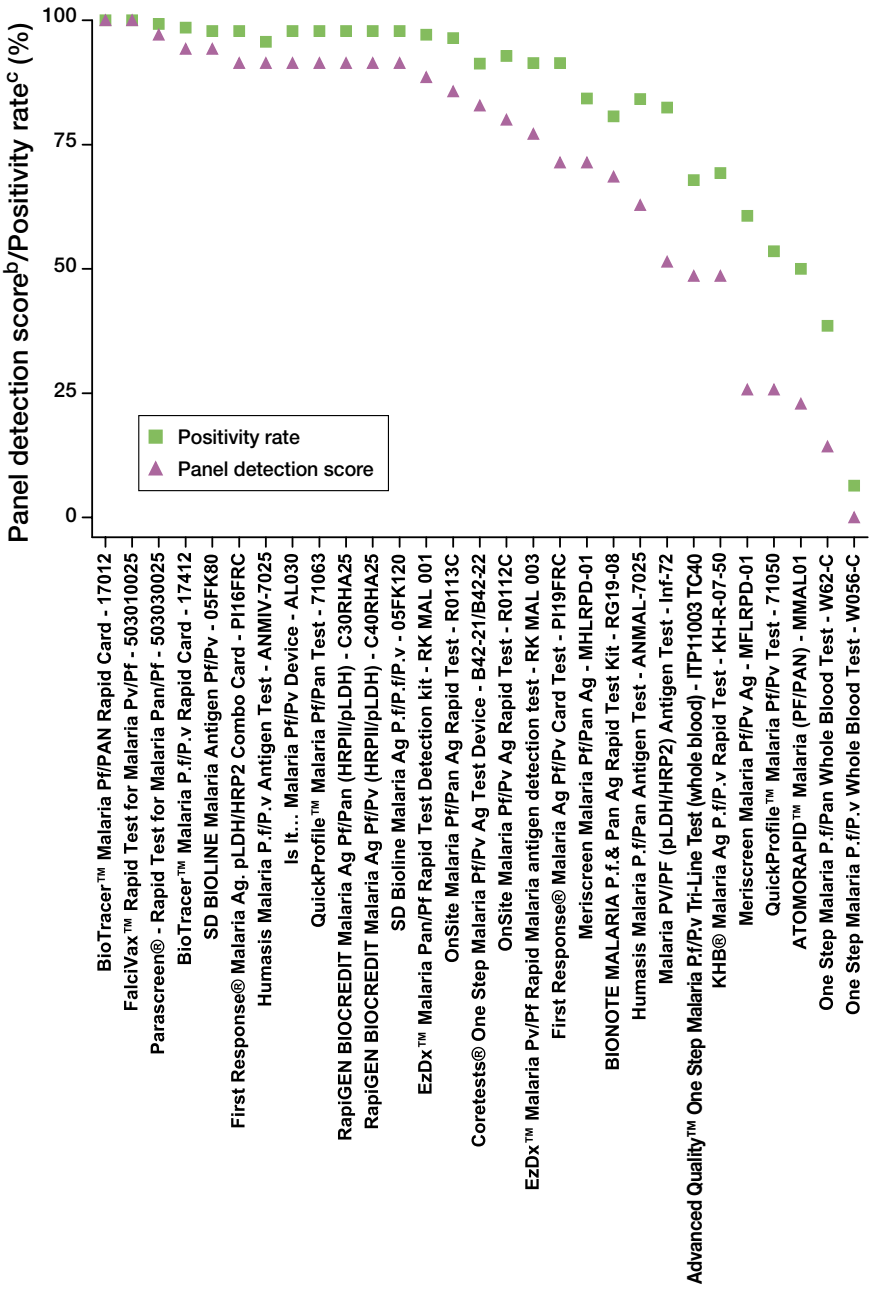
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive.

[c] The total number of times a test returned a positive result divided by the total number of times it should have (x100).

Of the combination RDT products containing a pan test band that gave a positive indication for *P. falciparum* against low-density *P. falciparum* samples, 47.1% (1105/2346) gave positive results on both the *P. falciparum* and pan test bands, and 51.8% (1216/2346) were positive only on the *P. falciparum* test band. A small proportion (1.1%, 25/2346) were positive only on the pan test band.

When the pan test band in the combination products was positive, the mean intensity of the band was 1.12 (standard deviation, 0.09), which was significantly lower than the corresponding mean *P. falciparum* test band intensity (mean, 2.33; standard deviation, 0.27), when tested against the lower-density *P. falciparum* parasite panel (paired *t* test, $p < 0.001$). Products with higher mean pan test band intensities tended to also have higher *P. falciparum* test band intensities, but this correlation did not reach statistical significance (Spearman $r = 0.385$, $p = 0.19$, $n = 13$).

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.

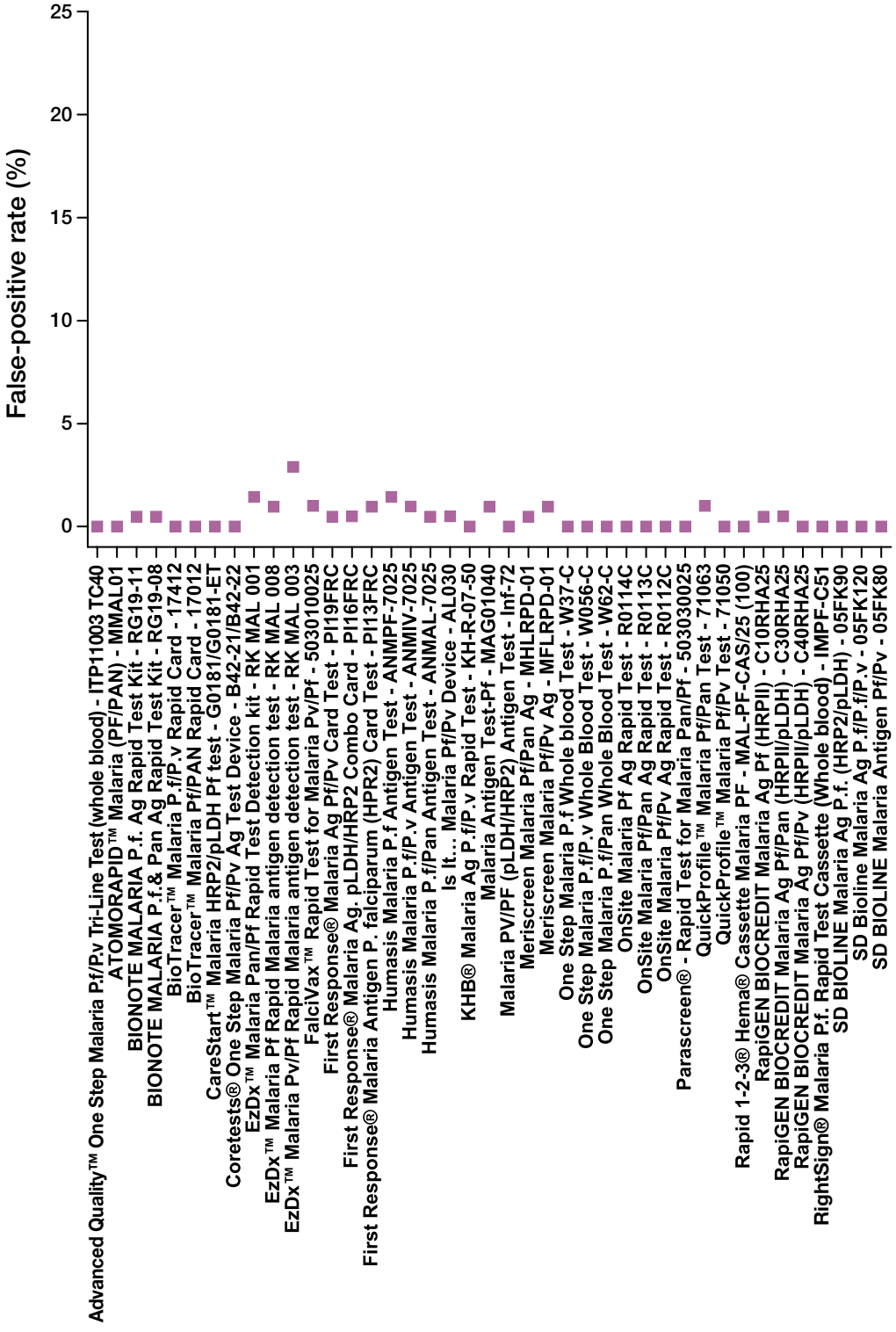
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

[c] The total number of times a test returned a positive result divided by the total number of times it should have (x100).

12.3.6 False-positive rates

No products had false-positive rates > 10% on 52 clean-negative samples for any test line (Figs 14 and 15). Eight products showed false-positivity rates between 5.2% and 8.6% (for one or both lots), against samples containing immunological factors, which is much lower than the rates in previous rounds. Only one product had a high false-positive rate (25.9%) against the immunological abnormality samples, which appeared to be lot-specific. False positivity in this category was predominantly against samples containing human anti-mouse antibodies.

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

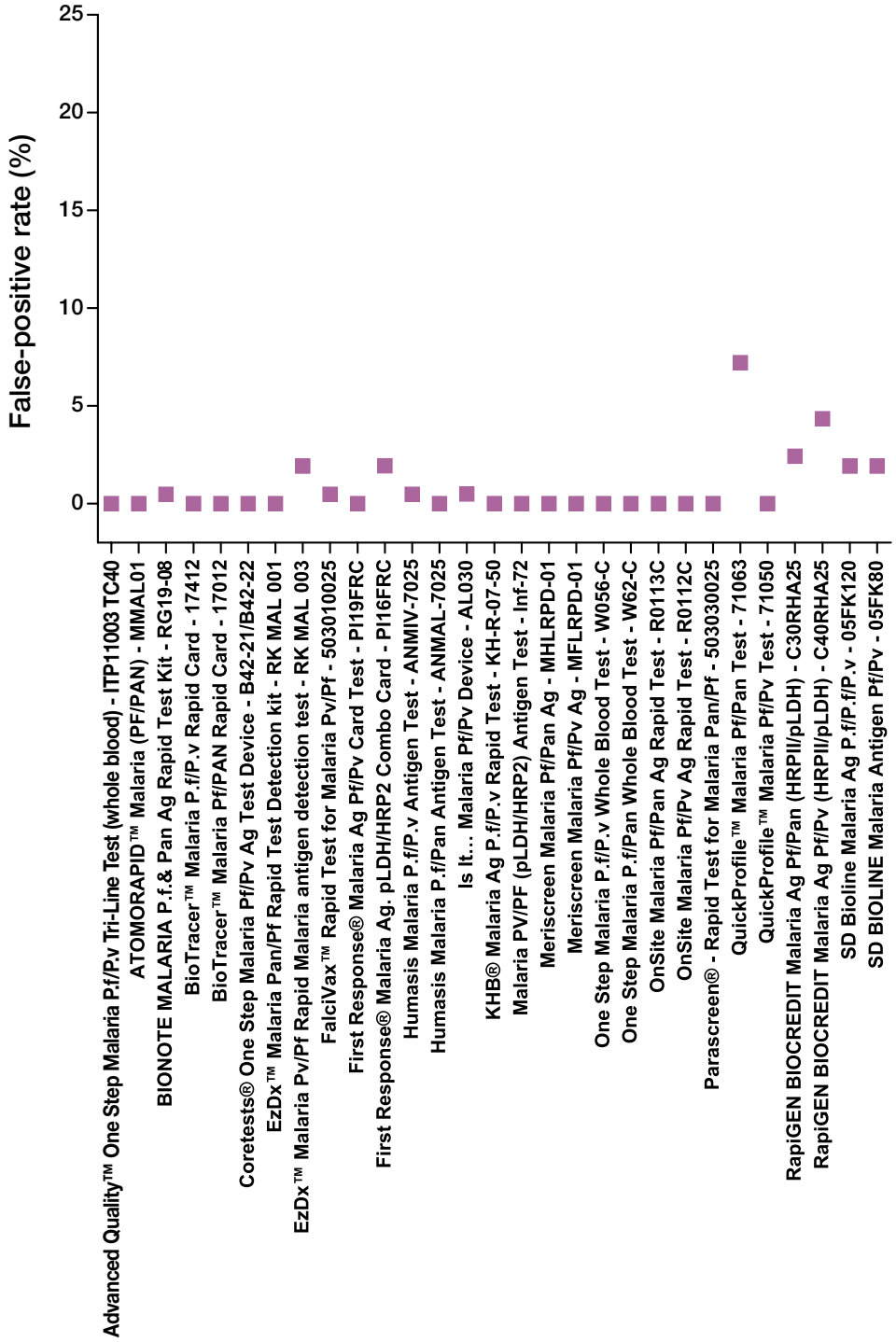


[a] Phase-2 evaluation panel included 100 *Plasmodium* spp.-negative samples, of which 52 were clean negatives from healthy volunteers with no known current illness or blood abnormality.

False-positivity rates against samples containing non-*Plasmodium* spp. infectious agents was much lower than in previous rounds. No products had high false-positivity rates, and five products showed false-positivity rates of 5.3–7.9% (for one or both lots). False positivity in this category was predominantly against schistosoma and dengue samples.

It is important to note only 19 samples contained non-*Plasmodium* infectious agents and 29 samples contained immunological factors. For detailed information on the blood abnormalities and pathogens that generated false-positive results in specific products, see Annex 4 (Tables A4.6–A4.9).

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

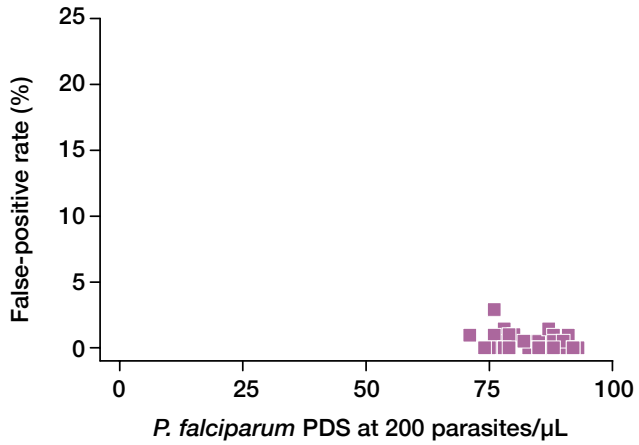


[a] Phase-2 evaluation panel included 100 *Plasmodium* spp.-negative samples of which 52 were clean negatives, from healthy volunteers with no known current illness or blood abnormality.

Products were assessed for false-positivity rates against species that they were not designed to detect (Tables A4.4 and A4.5). Overall, the rates were low, only one product showing > 10% false positivity for a *P. vivax* detecting line when tested against samples of *P. falciparum* at 2000 parasites/µL.

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

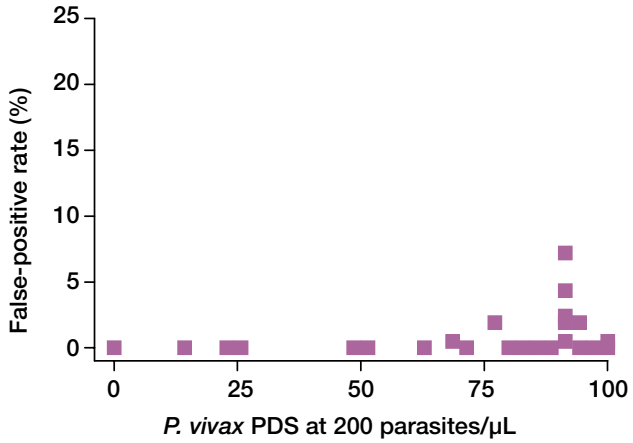
Figure 16: Phase-2 *P. falciparum* false-positive rate versus[a] *P. falciparum* panel detection score[b] at low parasite density (200 parasites/µL)



[a] False-positive rate is for clean-negative, 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 parasite density (200 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.

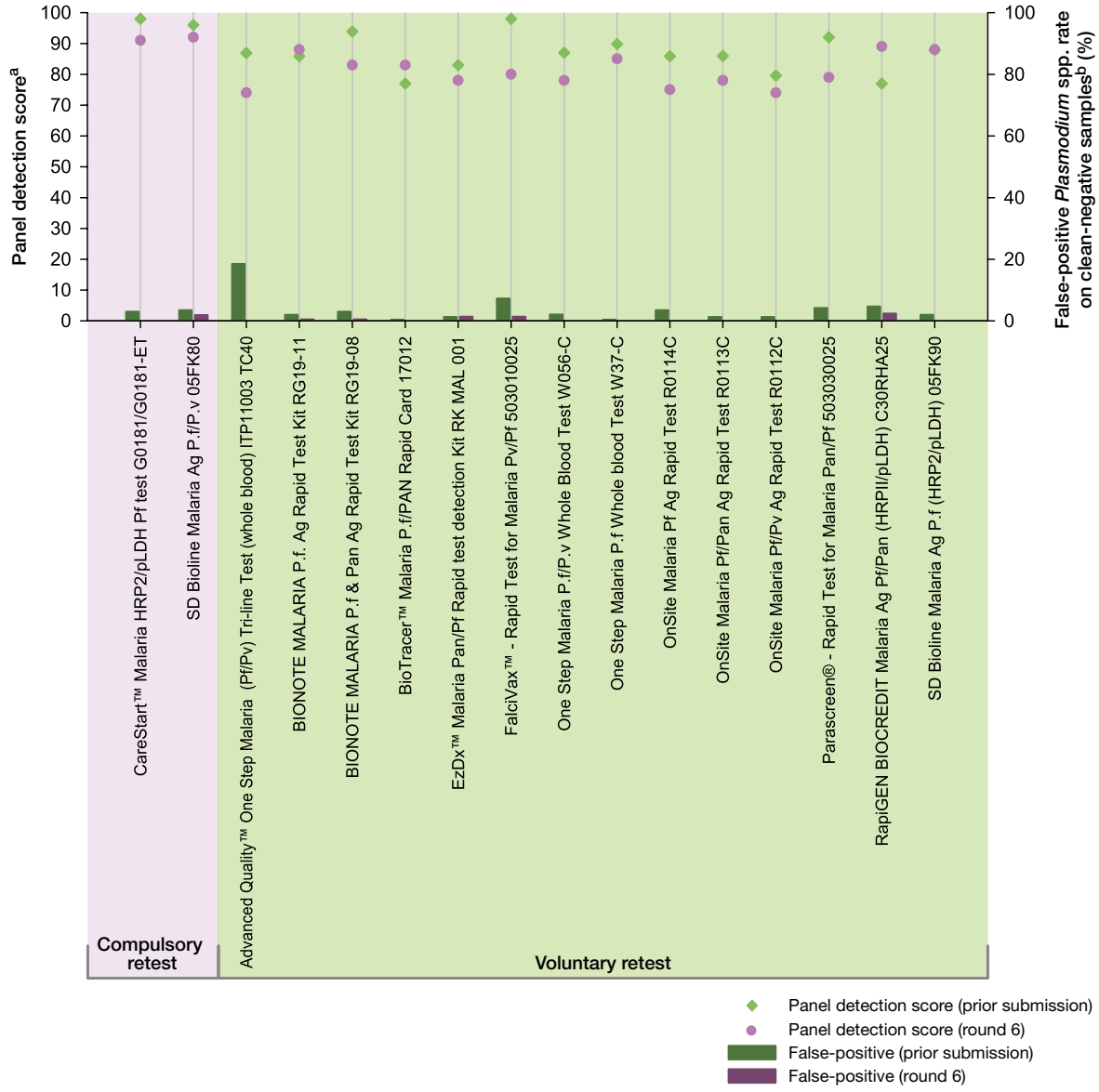
12.4. Performance of resubmitted products

Of the products in round 6, 39% had been evaluated previously. For nine of the resubmissions, this was the second testing, and seven had been tested more than twice. Figs 18 and 19 show the performance in the current and previous 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 two products that had not been tested since round 2 (compulsory resubmissions), the change in PDS between the two rounds was –7.0% and –4.0%. The *P. vivax*-detecting product showed a change in PDS of –0.7%.

For the 14 products that were voluntarily resubmitted for testing, there was no significant correlation between the PDS for *P. falciparum* at lower parasite density in consecutive submissions (Spearman rank correlation, $r = 0.067$, $p = 0.82$). The median change in detection of *P. falciparum* was –6.8% (range, –18.0 to 12.0%), which was significantly different

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

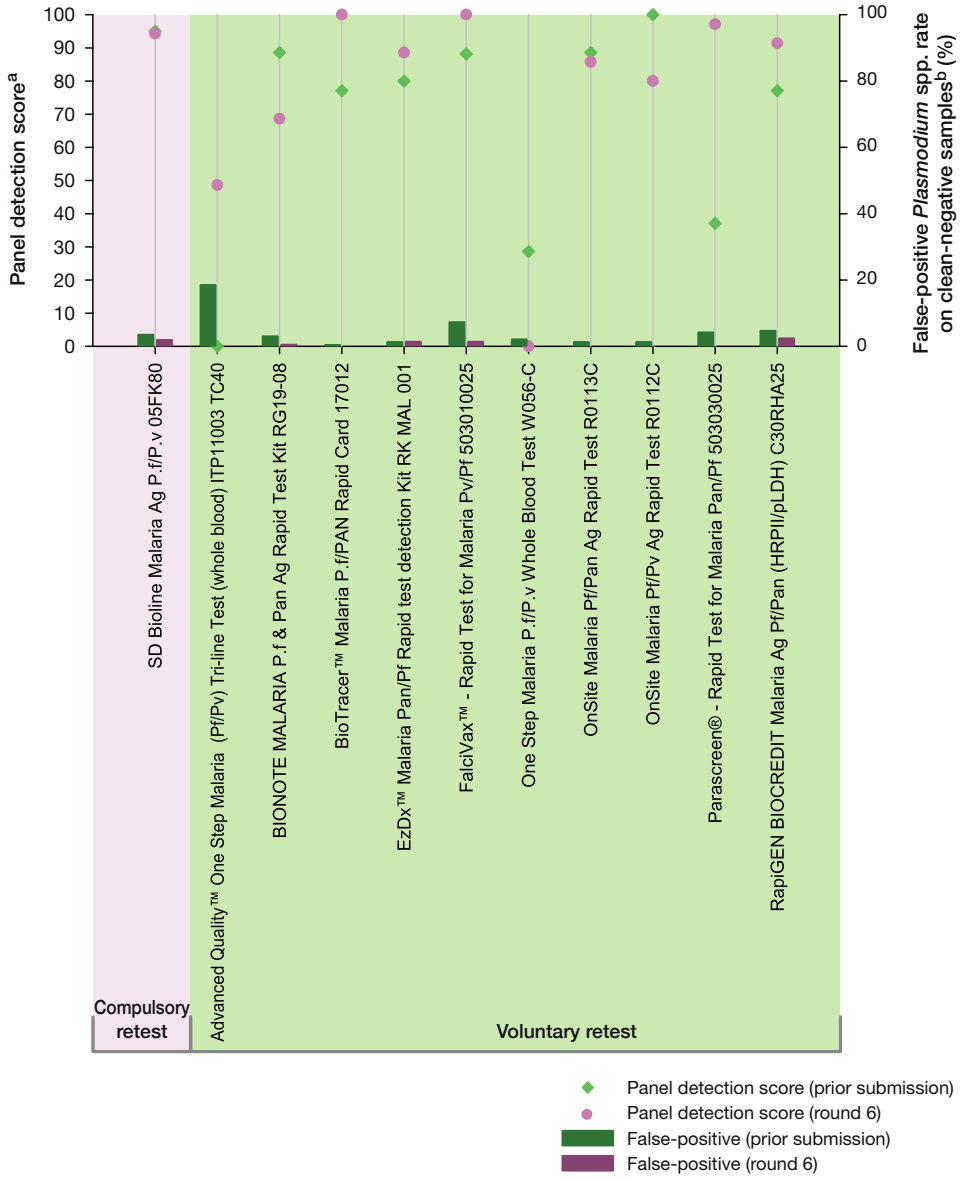


[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
[b] Clean-negative blood samples from healthy volunteers with no known current illness or blood abnormality.

from zero (Wilcoxon signed rank test, $p = 0.041$). Most of these products (10/16) detected *P. vivax*, and detection of this parasite improved slightly overall (median change, 10.2%; range, –28.6 to 60.0%); this change was not statistically significant (Wilcoxon signed rank test, $p = 0.44$). No correlation was found in the PDS against *P. vivax* at a lower parasite density of consecutive submissions (Spearman rank correlation, $r = 0.125$, $p = 0.73$).

On re-testing, all false-positivity rates were < 2.5%, and the majority of resubmitted products (15/16) showed an improvement in their false-positivity rate against the clean negative samples. The one product that did not improve increased by only 0.1%.

Figure 19: Phase-2 *P. vivax* panel detection score[a] at low parasite density (200 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

13.1. Summary

A single *P. falciparum* culture sample and single wild-type *P. vivax* sample were used as the reference samples to test heat stability. A wild-type *P. vivax* sample was used as continuous in vitro culturing of *P. vivax* is very difficult, largely because of the selective invasion of reticulocytes by the parasite. This is the first round in which the stability of test lines to detect non-*P. falciparum* parasites has been tested. Because of the large number of aliquots used to assess heat stability, fewer replicate RDTs were tested against *P. vivax*, with four assessed against the 200 parasites/µL sample and two against the 2000 parasites/µL sample, for each of the two lots. The results of heat stability testing are summarized in Tables 6a and 6b, and detailed results are presented in Annex 4 (Tables A4.10–A4.18) and in Figs. 20–29, which show the results for the two lots combined. The maximum scores were 30 (15 tests per lot) against *P. falciparum* for 200 parasites/µL and 10 for 2000 parasites/µL (five tests per lot). The maximum score against *P. vivax* was 8 for 200 parasites/µL (four tests per lot) and 4 for 2000 parasites/µL (two tests per lot).

Confirmatory data on the stability of recent production lots of all tests can be obtained from the manufacturers and through the WHO–FIND lot-testing programme during product selection for procurement of RDTs.

13.2. *Plasmodium falciparum*

Ten of 12 *P. falciparum*-only RDTs with an HRP2 test line 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 with (75% humidity) for 2 months (Fig. 20) as at baseline. Two products showed a slight loss in detection at 35 °C but not when stored at 45 °C. One *P. falciparum*-only detecting product had a line that detected *P. falciparum* pLDH (in addition to an HRP2 line). This product showed clear deterioration in detection after incubation only on the *P. falciparum* pLDH line.

The HRP2-detecting line of 20/29 combination tests was heat stable against a cultured *P. falciparum* sample. The other nine products showed only a slight loss in detection at one of the incubation times. One product detected both HRP2 and *P. falciparum* pLDH (on separate lines) and showed poor detection on the *P. falciparum* pLDH at baseline, and detection diminished after incubation.

Many combination test products had pan lines that poorly detected 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. Two of the three combination tests with good baseline pan line reactivity to the low-density sample showed good detection throughout, while one showed a marked reduction in performance after 2 months at 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. The stability of pan-pLDH-detecting test lines was much poorer than that of HRP2-detecting test lines (See Figs 20–25).

13.3. *Plasmodium vivax*

This was the first round to test the heat stability of *P. vivax* detecting lines. Many (8/13) combination RDTs with a pan-LDH test line were heat-stable when tested against a wild-type *P. vivax* sample. Tests with baseline positivity < 100% showed unpredictable variation in positivity rates on subsequent testing, indicating that they were on the borderline of detection. Some products showed improved detection after incubation, while others showed diminished detection.

The *P. vivax* pLDH line was less stable when tested against the *P. vivax* sample, but there was still a selection (5/16) of heat-stable combination products. Some of the remaining products had better detection after incubation, while others showed diminished detection, unpredictable variation or poor detection throughout (see Figs 26–29).

Overall, both *P. falciparum* and *P. vivax* detecting products were more stable against samples with high (2000 parasites/µL) rather than low (200 parasites/µL) parasite density, as minor deterioration will not be apparent at high parasite density.

Table 6a: Heat stability testing results for 41 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35 °C and 45 °C[a]

Product	Product code	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	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	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																		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	30	30	29 (29)	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	30	30	28	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	30 (30 / 28)[b]	30 (30 / 28)[b]	30 (30 / 27)[b]	30 (30 / 20)[b]	NA	NA	NA	NA	10 (10 / 10)[b]	10 (10 / 10)[b]	10 (10 / 10)[b]	10 (10 / 10)[b]	NA	NA	NA	NA
Pf and pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	30	30	30	29 (29)	0	0	5	0 (29)	10	10	10	10	10	10	10	10
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	30	30	30	30	0	0	0	0	10	10	10	10	10	10	10	10
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	30	30	30	30	30	27	28	20	10	10	10	10	10	10	10	10
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	30	30	30	30	1	9	7	3	10	10	10	10	10	10	10	10
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	30	30	30	30	29	27	30	21	10	10	10	10	10	10	10	10
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	30	30	30	30	0	0	0	0	10	10	10	10	10	10	10	10
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	29 (29)	30	29 (29)	29	27 (29)	20	28 (29)	11	9 (9)	10	10	10	9 (9)	9	10	9
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	30	30	30	30	14	24	17	0	10	10	10	10	10	10	10	10
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	30	30	30	29	0	0	0	0	10	10	10	10	9	9	10	7
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	30	30	30	30	0	0	2	0	10	10	10	10	10	10	10	10
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	30	30	30	30	30	27	27	28	10	10	10	10	10	10	10	10
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	30	30	30	30	30	29	29	30	10	10	10	10	10	10	10	10
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	30	30	30	29	0	1	3	8	10	10	10	10	10	10	10	10
Pf and Pv																		
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	29	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA

(continued)

Table 6a: Heat stability testing results for 41 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35 °C and 45 °C[a] *(continued)*

Product	Product code	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	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C
			Number of tests positive (max. 30)				Number of tests positive (max. 30)				Number of tests positive (max. 10)				Number of tests positive (max. 10)			
			Lots 1 and 2 combined				Lots 1 and 2 combined				Lots 1 and 2 combined				Lots 1 and 2 combined			
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	30	30	29 (29)	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	30	30	30	29 (29)	NA	NA	NA	NA	9 (9)	10	10	10	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	30	29 (29)	30	28 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	30	30	30	30	NA	NA	NA	NA	9 (9)	10	10	10	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	29 (29)	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	30	30	30	29 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	30 (30 / 9)[b]	30 (30 / 23)[b]	30 (30 / 9)[b]	30 (30 / 9)[b]	NA	NA	NA	NA	10 (10 / 10)[b]	10 (10 / 10)[b]	10 (10 / 10)[b]	10 (10 / 10)[b]	NA	NA	NA	NA

NA, not applicable

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

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

[b] Product result shown along with results for HRP2 band and Pf-pLDH band, respectively

Table 6b: Heat stability testing results for 29 combination malaria RDTs on a wild-type *P. vivax* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35 °C and 45 °C[a]

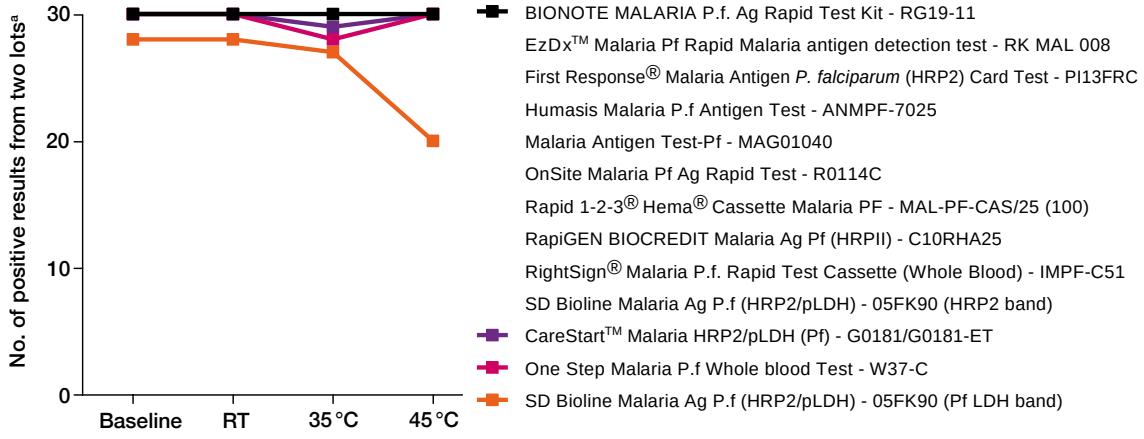
Product	Product code	Manufacturer	Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (pan line)				Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (pan line)			
			200 parasites/µL				200 parasites/µL				2000 parasites/µL				2000 parasites/µL			
			Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C	Baseline	Room temp	35 °C	45 °C
			Number of tests positive (max. 8) Lots 1 and 2 combined				Number of tests positive (max. 8) Lots 1 and 2 combined				Number of tests positive (max. 4) Lots 1 and 2 combined				Number of tests positive (max. 4) Lots 1 and 2 combined			
Pf and pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	NA	NA	NA	NA	3	5	7	5	NA	NA	NA	NA	4	4	4	4
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	NA	NA	NA	NA	6	8	8	7	NA	NA	NA	NA	4	4	4	4
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	NA	NA	NA	NA	6	8	7	6	NA	NA	NA	NA	4	4	4	4
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	NA	NA	NA	NA	5	8	7	2	NA	NA	NA	NA	4	4	4	4
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	NA	NA	NA	NA	2	0	2	1	NA	NA	NA	NA	4	4	4	4
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Pf and Pv																		
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	2	6	6	7	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	8	8	8	7	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	8	7	5	3	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	8	7 (7)	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	4	8	6	6	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	8	8	7	2	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1	5	2	0	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	8	8	8	7	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	3	0	0	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Pf, Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	8	8	7 (7)	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA

NA, not applicable

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

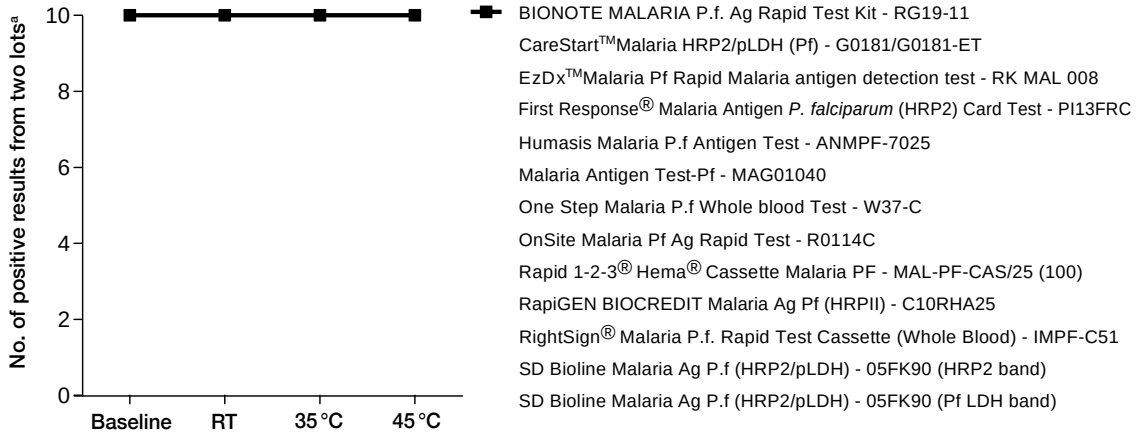
[a] Positive results presented in the table are based on stability of a positive reader 1 result

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



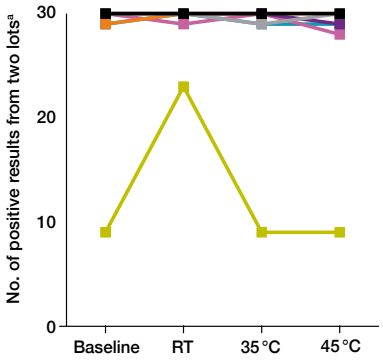
[a] Maximum score is 30 (15 tests x 2 lots)

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);

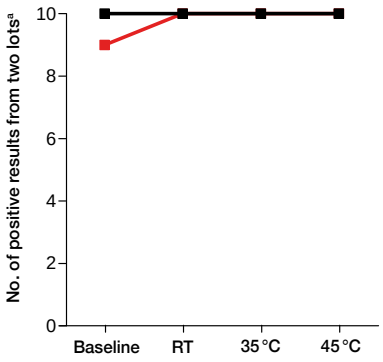
Figure 22: Heat stability of *P. falciparum*-specific test line in combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
- BioTracer™ Malaria P.f/P.v Rapid Card - 17412
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
- EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
- EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
- First Response® Malaria Ag. pLDH/HRP2 Combo Card - PI16FRC
- Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
- Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
- KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
- Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
- Meriscreen Malaria Pf/Pv Ag - MFLRPD-01
- One Step Malaria P.f/P.v Whole Blood Test - W056-C
- OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
- OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
- Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
- QuickProfile™ Malaria Pf/Pan Test - 71063
- QuickProfile™ Malaria Pf/Pv Test - 71050
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120 (HRP2 band)
- Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test (whole blood) - ITP11003 TC40
- RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
- ATOMORAPID™ Malaria (PF/PAN) - MMAL01
- First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
- One Step Malaria P.f/Pan Whole Blood Test - W62-C
- RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- SD BIOLINE Malaria Antigen Pf/Pv - 05FK80
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- Is It… Malaria Pf/Pv Device - AL030
- Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120 (Pf LDH band)

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

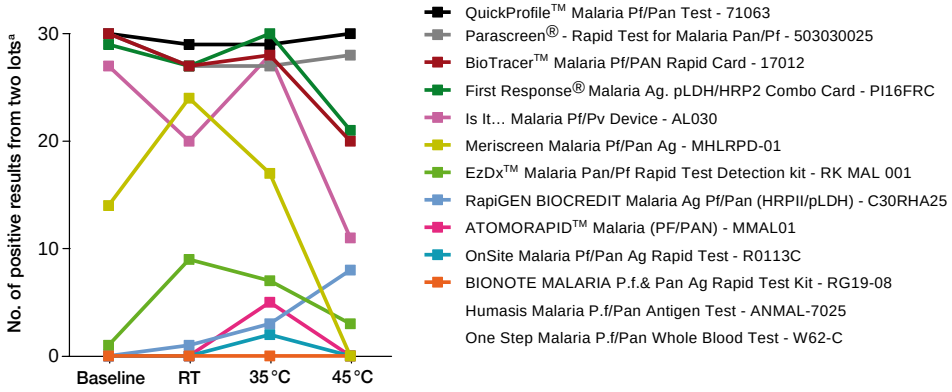
Figure 23: Heat stability of *P. falciparum*-specific test line in combination tests against a high-density *P. falciparum* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test (whole blood) - ITP11003 TC40
- ATOMORAPID™ Malaria (PF/PAN) - MMAL01
- BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- BioTracer™ Malaria P.f/P.v Rapid Card - 17412
- Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
- EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
- EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- First Response® Malaria Ag. pLDH/HRP2 Combo Card - PI16FRC
- Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
- Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
- KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
- Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
- Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
- Meriscreen Malaria Pf/Pv Ag - MFLRPD-01
- One Step Malaria P.f/Pan Whole Blood Test - W62-C
- One Step Malaria P.f/P.v Whole Blood Test - W056-C
- OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
- Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
- QuickProfile™ Malaria Pf/Pan Test - 71063
- QuickProfile™ Malaria Pf/Pv Test - 71050
- RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25
- RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
- SD BIOLINE Malaria Antigen Pf/Pv - 05FK80
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120 (HRP2 band)
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120 (Pf LDH band)
- First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
- Is It… Malaria Pf/Pv Device - AL030
- OnSite Malaria Pf/Pv Ag Rapid Test - R0112C

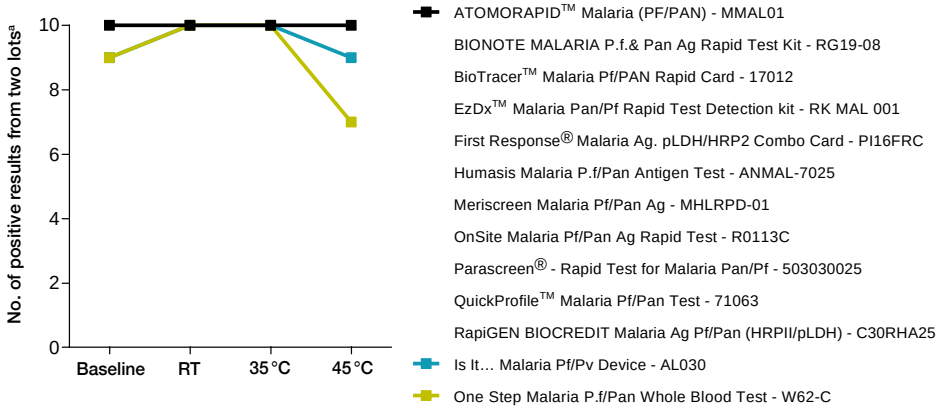
[a] Maximum score is 10 (5 tests x 2 lots)

Figure 24: Heat stability of pan line of combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



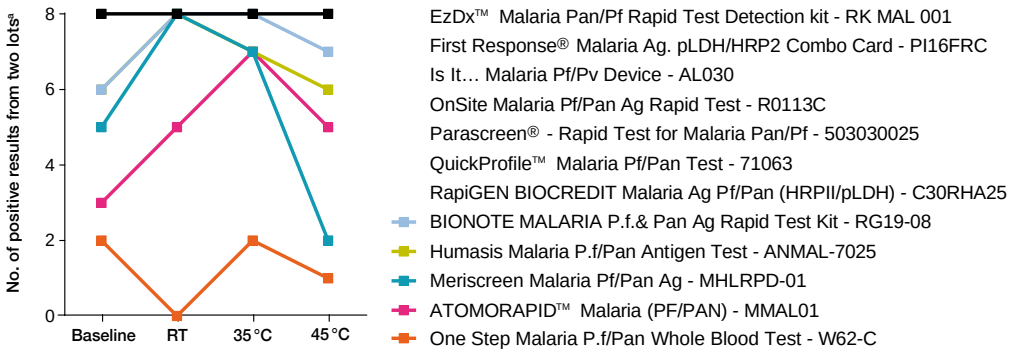
[a] Maximum score is 30 (15 tests x 2 lots)

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



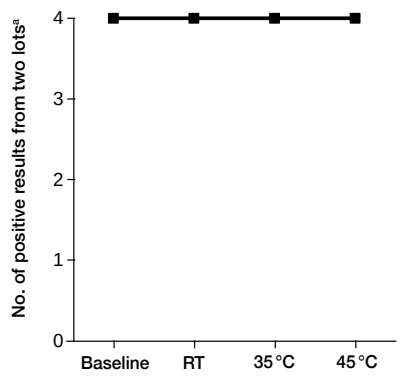
[a] Maximum score is 10 (5 tests x 2 lots)

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



[a] Maximum score is 8 (4 tests x 2 lots)

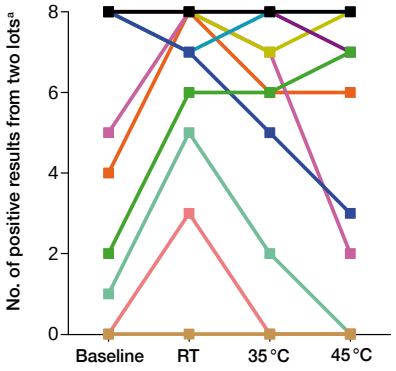
Figure 27: Heat stability of pan line of combination tests against a high-density *P. vivax* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation



- ATOMORAPID™ Malaria (PF/PAN) - MMAL01
- BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit - RG19-08
- BioTracer™ Malaria Pf/PAN Rapid Card - 17012
- EzDx™ Malaria Pan/Pf Rapid Test Detection kit - RK MAL 001
- First Response® Malaria Ag. pLDH/HRP2 Combo Card - PI16FRC
- Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
- Is It… Malaria Pf/Pv Device - AL030
- Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
- One Step Malaria P.f/Pan Whole Blood Test - W62-C
- OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
- Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
- QuickProfile™ Malaria Pf/Pan Test - 71063
- RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C30RHA25

[a] Maximum score is 4 (2 tests x 2 lots)

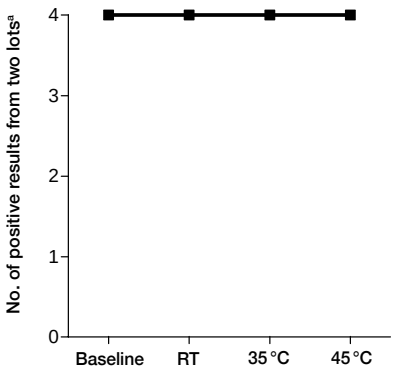
Figure 28: Heat stability of *P. vivax*-specific test line in combination tests against a low-density *P. vivax* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- BioTracer™ Malaria P.f/P.v Rapid Card - 17412
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
- RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
- SD BIOLINE Malaria Antigen Pf/Pv - 05FK80
- Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
- OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
- Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120
- KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
- EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
- Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
- Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test (whole blood) - ITP11003 TC40
- Meriscreen Malaria Pf/Pv Ag - MFLRPD-01
- QuickProfile™ Malaria Pf/Pv Test - 71050
- One Step Malaria P.f/Pan Whole Blood Test - W62-C

[a] Maximum score is 8 (4 tests x 2 lots)

Figure 29: Heat stability of *P. vivax*-specific test line in combination tests against a high-density *P. vivax* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Advanced Quality™ One Step Malaria P.f/P.v Tri-Line Test (whole blood) - ITP11003 TC40
- BioTracer™ Malaria P.f/P.v Rapid Card - 17412
- Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
- EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
- Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
- KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
- Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
- Meriscreen Malaria Pf/Pv Ag - MFLRPD-01
- One Step Malaria P.f/Pan Whole Blood Test - W62-C
- OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
- QuickProfile™ Malaria Pf/Pv Test - 71050
- RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
- SD BIOLINE Malaria Antigen Pf/Pv - 05FK80
- SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120

[a] Maximum score is 4 (2 tests x 2 lots)

14. EASE-OF-USE DESCRIPTION AND ANOMALIES

14.1. Ease of use

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 manufacturer 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).

14.2. Anomalies

In round 6, 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 percentage of tests per product for which specific anomalies were observed and the frequency of tests with an anomaly for each 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. Each round-6 product had one to six anomalies (Table 8). Incomplete clearing and red background were the most commonly observed anomalies, seen in 95% and 85% of products, respectively. Failed migration, incomplete migration and patchy broken test lines were the next most regularly reported, seen in 34%, 32% and 37% of products, respectively. Overall, approximately half the products had a frequency of anomalies > 2% (Fig. 30).

Figure 30: Percentage of RDTs with various anomalies observed in production lots

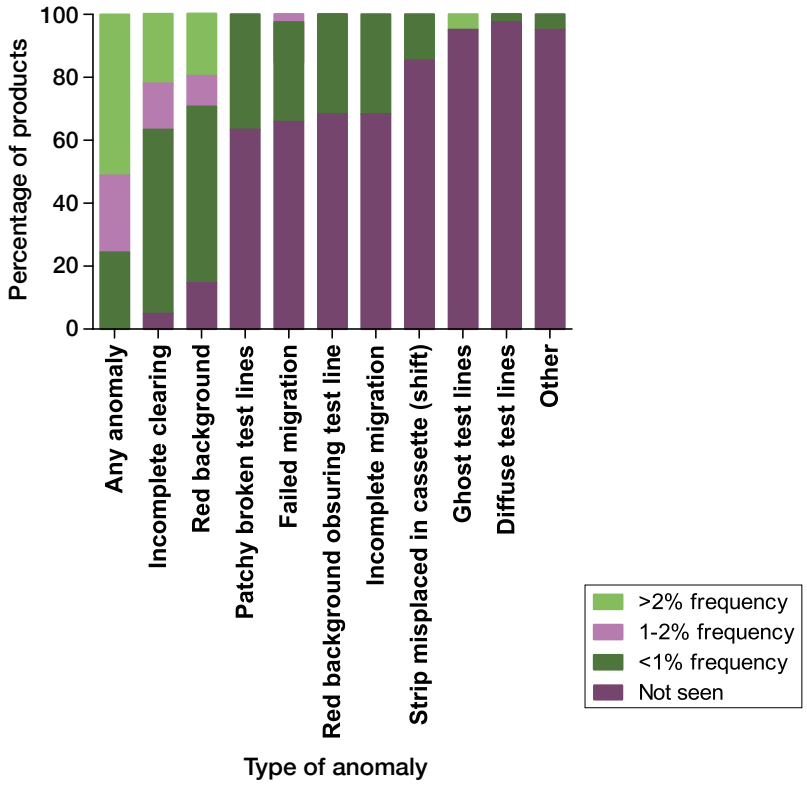


Table 7: Ease-of-use description of 41 malaria RDTs included in round 6: WHO malaria RDT product testing

Product	Product code	Manufacturer	Blood safety[a]				Instruction quality[b]				Combined score (max.5)	Number of timed steps	Total time to result	Desiccant with color indicator (yes/no)	Buffer					Blood transfer device	Format	Language of instruction	Items included in RDT box[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)					Container does not puncture	Does not flow freely	insufficient volume	empty (bottle or vial)	discoloured				
Pf only																							
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English, French, Spanish	cassette/IFU/buffer bottle/alcohol swab / lancet
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	1	NA	1	2			2	2	4	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1	2			2	2	4	1	15	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	1	NA	1	2			2	2	4	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	1	0	1	2		1		1	3	1	20	no						loop	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	1	0	1	2			2	2	4	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	1	NA	1	2			2	2	4	1	10	no						pipette	cassette	English	cassette/IFU/buffer bottle
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	1	0	1	2			2	2	4	1	15	yes						pipette	cassette	English, French	cassette/IFU/buffer bottle/alcohol swab / lancet
Pf and pan																							
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	1	1	1	3			2	2	5	1	15	no						collection arm	cassette	English	cassette/IFU/buffer bottle
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	1	NA	1	2			2	2	4	1	20	no						loop	cassette	English	cassette/IFU/buffer bottle
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English, French, Spanish	cassette/IFU/buffer bottle/alcohol swab / lancet
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	1	NA	1	2		1		1	3	1	20	no	X	X				loop	cassette	English	cassette/IFU/buffer bottle
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	1	NA	1	2		1		1	3	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1	2			2	2	4	1	15	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	1	NA	1	2			2	2	4	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	1	0	1	2			2	2	4	1	20	no	X					loop	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	1	0	1	2			2	2	4	1	20	no			X			pipette	cassette	English	cassette/IFU/buffer bottle
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	1	0	1	2			2	2	4	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle

Table 7: Ease-of-use description of 41 malaria RDTs included in round 6: WHO malaria RDT product testing *(continued)*

Product	Product code	Manufacturer	Blood safety[a]				Instruction quality[b]				*Combined score* (max. 5)	Number of timed steps	Total time to result	Desiccant with color indicator (yes/no)	Buffer					Blood transfer device	Format	Language of instruction	Items included in RDT box[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)					Container does not puncture	Does not flow freely	insufficient volume	empty (bottle or vial)	discoloured				
Pf and Pv																							
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	1	0	1	**2**			2	**2**	**4**	1	15	no						pipette	cassette	English	cassette/IFU/buffer bottle
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	1	NA	1	**2**			2	**2**	**4**	1	20	no						loop	cassette	English	cassette/IFU/buffer bottle
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	1	0	1	**2**		1		**1**	**3**	1	15	no	X					pipette	cassette	English	cassette/IFU/buffer bottle
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	1	0	1	**2**			2	**2**	**4**	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1	0	1	**2**			2	**2**	**4**	1	20	no	X					loop	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	1	0	1	**2**			2	**2**	**4**	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	1	0	1	**2**			2	**2**	**4**	1	20	no						inverted cup	cassette	English, French, Spanish	cassette/IFU/buffer bottle/alcohol swab / lancet
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	1	1	1	**3**			2	**2**	**4**	1	15	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	1	NA	1	**2**			2	**2**	**4**	1	20	no						pipette	cassette	English	cassette/IFU/individual buffer vials/alcohol swab / lancet
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1	NA	1	**2**		1		**1**	**3**	1	20	no						pipette	cassette	English	cassette/IFU/buffer bottle
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1	**2**			2	**2**	**4**	1	15	no						pipette	cassette	English	cassette/IFU/buffer bottle/alcohol swab / lancet
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	1	NA	1	**2**			2	**2**	**4**	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	1	0	1	**2**			2	**2**	**4**	1	20	no			X			pipette	cassette	English	cassette/IFU/buffer bottle
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	1	0	1	**2**			2	**2**	**4**	1	30	no						pipette	cassette	English	cassette/IFU/buffer bottle
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	1	0	1	**2**			2	**2**	**4**	1	15	yes						pipette	cassette	English, French	cassette/IFU/buffer bottle/alcohol swab / lancet
Pf and Pf and Pv																							
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	1	0	1	**2**			2	**2**	**4**	1	15	yes						pipette	cassette	English, French	cassette/IFU/buffer bottle/alcohol swab / lancet

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

IFU, instructions for use

[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] Procurers should verify which accessories accompany test kits with the manufacturer and ensure they procure the appropriate products.

Table 8: Percentage distribution of anomalies observed by product in phase 2

Product	Product code	Manufacturer	Percentage of tests with at least one anomaly	Percentage of tests with specified anomaly									
				Red background	Red background obsuring test line(s)	Incomplete clearing	Incomplete migration	Failed migration	Strip misplaced in cassette (shift)	Ghost test lines	Diffuse test lines	Patchy broken test line	Other
Pf only													
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.5	0.0	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.2	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0.7	0.1	0.0	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	2.0	0.7	0.0	1.3	0.0	0.1	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	1.5	0.5	0.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0.2	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	3.0	0.4	0.2	2.3	0.2	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	5.9	5.8	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	1.1	0.0	0.0	0.8	0.0	0.2	0.0	0.0	0.0	0.2	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0.6	0.2	0.1	0.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0.4	0.0	0.0	0.1	0.0	0.3	0.0	0.0	0.0	0.0	0.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	1.6	1.1	0.0	0.4	0.0	0.0	0.1	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	6.6	0.2	0.2	1.7	0.0	0.0	0.0	4.6	0.0	0.0	0.0
Pf and pan													
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	9.8	3.7	0.1	5.9	0.0	0.0	0.0	0.0	0.0	0.2	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.5	0.0	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.4	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	2.9	1.9	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.5	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	1.9	0.7	0.0	1.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	1.4	0.8	0.0	0.6	0.0	0.1	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.6	0.3	0.0	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	8.1	3.3	0.4	3.6	0.6	0.2	0.0	0.0	0.0	0.0	0.1
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	1.4	0.6	0.0	0.8	0.0	0.0	0.0	0.0	0.0	0.1	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	5.6	5.3	0.1	0.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	2.3	0.5	0.0	1.3	0.0	0.2	0.1	0.0	0.0	0.3	0.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.5	0.2	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	9.2	0.1	0.2	8.8	0.1	0.0	0.0	0.0	0.1	0.0	0.1
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	0.4	0.2	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.0	0.0
Pf and Pv													
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	31.5	29.7	0.1	1.0	0.2	0.4	0.2	0.0	0.0	0.2	0.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	2.2	1.1	0.0	0.8	0.1	0.0	0.0	0.0	0.0	0.2	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	6.7	2.0	0.2	3.8	0.1	0.6	0.0	0.0	0.0	0.1	0.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	3.7	1.8	0.0	1.7	0.1	0.0	0.1	0.0	0.0	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1.3	0.2	0.2	1.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	1.6	0.9	0.0	0.5	0.0	0.2	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	1.1	0.2	0.0	0.8	0.0	0.1	0.0	0.0	0.0	0.0	0.0

Table 8: Percentage distribution of anomalies observed by product in phase 2 *(continued)*

Product	Product code	Manufacturer	Percentage of tests with at least one anomaly	Percentage of tests with specified anomaly									
				Red background	Red background obsuring test line(s)	Incomplete clearing	Incomplete migration	Failed migration	Strip misplaced in cassette (shift)	Ghost test lines	Diffuse test lines	Patchy broken test line	Other
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	2.9	0.1	0.0	2.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	16.2	11.0	0.5	3.5	0.1	1.2	0.0	0.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1.1	0.5	0.0	0.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	6.2	5.7	0.0	0.4	0.0	0.1	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	2.1	0.3	0.0	1.4	0.1	0.1	0.0	0.0	0.0	0.2	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	9.6	0.4	0.2	8.9	0.1	0.0	0.0	0.0	0.0	0.1	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.2	0.0	0.0	0.0	0.0	0.0	0.2	0.0	0.0	0.1	0.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	3.6	0.3	0.0	3.2	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pf and Pv													
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	98.0	0.2	0.1	0.8	0.0	0.0	0.0	97.4	0.0	0.1	0.0

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

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 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 the populations of most malaria-endemic countries.

Overall, the mean product PDS against low-density *P. falciparum* samples in round 6 was 83.6%, slightly higher than in round 5 (81.0%) but suggesting that performance may be plateauing after several rounds of improvement[1]. For *P. vivax*, the mean PDS of 70.7% is the highest achieved so far[2]. The median false-positive rate was 0.5%, which is a slight improvement over previous rounds. Overall, a high level of performance has been maintained in *P. falciparum*-only tests and improved performance has been seen in *P. vivax*-detecting RDTs.

Two products tested in round 2 of the programme were resubmitted for testing in round 6. Their performance was comparable 5 years after initial testing, both products fulfilling the WHO procurement criteria in both rounds.

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 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 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 (*10*).

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 16.2).

(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, and other issues, such as required storage conditions, stability, cost, experience and training of the intended users, ease of use (Annex S2) and manufacturing capacity, may be equally important in test selection.** Consideration of the parasite density

[1] PDS for *P. falciparum* in rounds 1, 2, 3 and 4 was 67.2%, 69.9%, 75.5% and 81.6%, respectively.

[2] PDS for *P. vivax* in rounds 1, 2, 3 , 4 and 5 was 36.0%, 58.9%, 47.1%, 51.3% and 61.3%, respectively.

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 (*11–12*). 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 in 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 6 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 (see Annex 1) 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 52 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. Published in Malaria Journal.

15.4. Heat (thermal) stability

In this round, heat stability of *P. vivax* detecting test lines was assessed against a wild-type *P. vivax* sample for the first time. The RDTs evaluated were held for 2 months at room temperature (21–25 °C) and at 35 °C and 45 °C at 75% humidity and tested to evaluate stability at these temperatures as compared with baseline detection. 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 (Annex 1). 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 desiccant and 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.

Several *P. falciparum* detecting 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. When tested against *P. vivax*, approximately half the pan-pLDH lines had high stability at all temperatures and times tested. While some products showed high stability on their *P. vivax* pLDH lines, they were generally less stable, performing less well at baseline and therefore making it difficult to assess stability after incubation.

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 period 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

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 but 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 micropipette 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).

15.6. RDT anomalies in production lots

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 4095 lots tested in the WHO–FIND lot testing programme, a glossary of RDT anomalies has been prepared (Fig. 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.

15.7. 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 16.2).

Inter-test variation 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 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[1].

15.8. 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 (*11,12*). Three *P. falciparum* RDT products were evaluated in round 6 that detected both *P. falciparum* pLDH and HRP2; however, detection of *P. falciparum* pLDH was less sensitive than detection of HRP2 at low parasite density; therefore, low density infections with HRP2-deleted *P. falciparum* parasites could be missed.

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) result in a high false-positive rate in areas where early retesting in the weeks immediately after treatment is common. As mentioned in section 2.3, 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 (*3–7*).

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 that for *P. falciparum* and *P. vivax* (*39*).

[1] http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/malaria_specimen_bank/en/

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, S3 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 on the FIND website and has now been updated to allow rapid identification of products with the same blood volume, number of buffer drops and time until reading[1]. Annex 1 also groups products according to similar procedure characteristics. 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* (*14*) and *Universal access to malaria diagnostic testing* (*15*).

While malaria RDTs can be used in a number of settings, the greatest impact on public health will ensue from 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 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. In order for an RDT programme to have its full potential public health impact, it 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.

16.1. Beyond performance

The WHO Prequalification of In Vitro Diagnostics Programme promotes access to good quality in vitro diagnostic tests by applying the principles of a comprehensive regulatory assessment. This includes inspection of the manufacturer's quality management system, including post-market surveillance, assessment of technical documentation (dossier review) and an independent performance evaluation.

The results of the WHO malaria product testing programme fulfil the performance evaluation component of the prequalification process. Although, prequalification is not currently a requirement for eligibility for United Nations procurement tenders for malaria RDTs, it is for other RDTs, such as for HIV. At present, 12 malaria RDT products are prequalified[2], and the WHO Global Malaria Programme is assessing the impact of requiring WHO prequalification for procurement. Manufacturers are advised that prequalification may be a future requirement in order to be eligible for WHO procurement, and are therefore encouraged to apply.

16.2. 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 in Annexes S2 and S3 to guide decisions.

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 (*15*).

[1] An interactive guide designed to short-list tests according to programme needs, based on the performance of tests in rounds 3–6 of the WHO product testing programme, can be found at: http://www.finddiagnostics.org/programs/malaria-afs/malaria/current-projects/rdt_quality_control/interactiveguide-intro/interactive-guide/index.jsp (accessed 10 September 2015).

[2] http://www.who.int/diagnostics_laboratory/evaluations/151103_prequalified_products_list.pdf?ua=1 (accessed 9 November 2015)

16.3. Post-market surveillance: lot verification

Post-market surveillance confirms manufacturer compliance with quality expectations and is an important component of any quality assurance scheme. Specifically for malaria RDTs, post-market surveillance ensures that the quality reported in product testing is found in what is available on the market to the user. Post-market surveillance can be performed proactively through lot verification (described next), which is recommended to all procurers, or reactively through completion of a " WHO user complaint form for reporting problems and/or adverse events related to diagnostic products" and submitted to the following email address: *diagnostics@who.int*.

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 all purchasers, including national malaria programmes, manufacturers and procurement bodies, to assess the quality of RDT lots before purchase or, when they arrive in a country, before distribution 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 and helps to ensure that manufacturers produce consistently good lots and improve their products. The results support decisions for accepting or rejecting lots. Lot testing provides information about the adequacy of RDTs for clinical use, their stability over their shelf life and any anomalies observed during testing that may also be encountered in the field.

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 (Fig. 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*). As lot-to-lot variation has previously been noted in many products, purchasers are encouraged to participate in the lot-testing programme to confirm the quality of RDT lots prior to use. Certain anomalies resulting from defects in production lots or RDT degradation may affect the running of the test or interpretation and may warrant a field safety notice and corrective action. In such instances, a special lot testing service can be provided, which is determined case by case.

Lot testing is free of charge, but the requester must cover shipping costs, including related tax and duties. To access lot testing through the WHO-FIND programme, contact *Malaria_rdt@who.int* and *Nora.Champouillon@finddx.org*, at least 2 weeks before RDTs are ready for shipment.

17. CONCLUSIONS

This report adds to the large data set on malaria RDT performance published annually since 2009 (*3–7*). 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 histidine-rich 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 6 adds to the number of well-performing RDTs for which comprehensive performance data are now available and provides updated data on 16 product resubmissions.

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ANNEXES

Annex S1: Characteristics of evaluation panels used in rounds 1–6 of WHO malaria RDT product testing, 2008–2015

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 six performance evaluation panels. No statistically significant differences were seen (Kruskal-Wallis test; $p > 0.5$), 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.

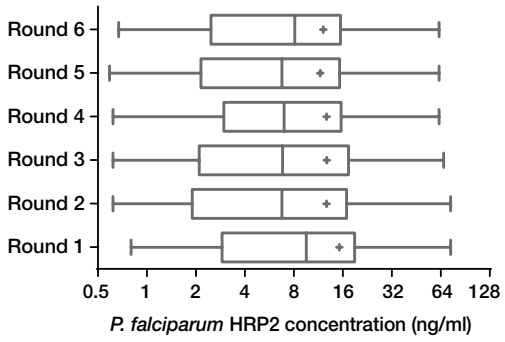


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

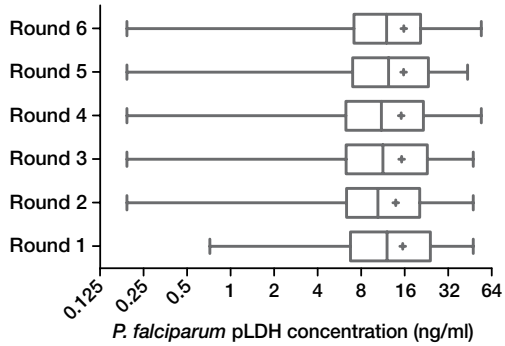


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

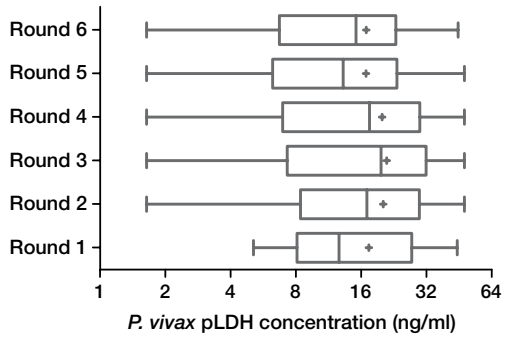


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

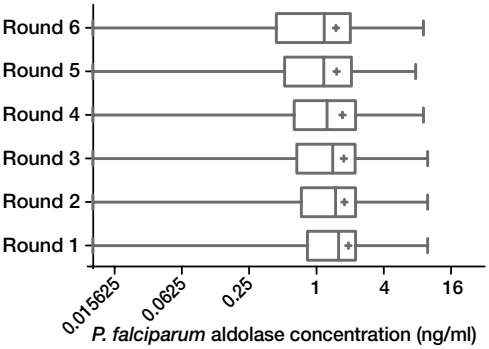


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

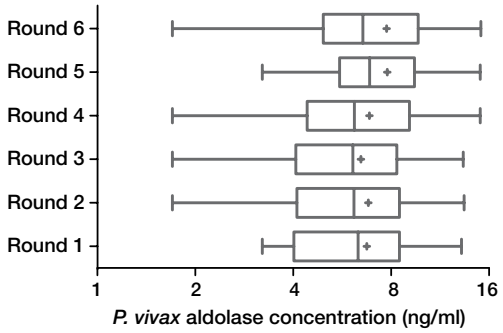


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
Number of values[a]	78	99	99	98	99	99
Minimum	0.80	0.62	0.62	0.62	0.59	0.67
25th percentile	2.90	1.90	2.10	2.97	2.15	2.48
Median	9.57	6.76	6.83	6.98	6.76	8.12
75th percentile	18.94	16.91	17.37	15.65	15.31	15.51
Maximum	73.70	73.70	66.70	62.48	62.48	62.48
Mean	15.28	12.70	12.77	12.72	11.65	12.15
Std. Deviation	16.98	15.75	15.19	14.72	13.25	13.29

[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	Round 6
Number of values[a]	74	93	92	92	94	98
Minimum	0.71	0.19	0.19	0.19	0.19	0.19
25th percentile	6.68	6.27	6.23	6.20	6.90	7.04
Median	11.95	10.31	11.18	10.92	12.24	11.85
75th percentile	23.75	20.10	22.70	21.28	23.05	20.36
Maximum	47.15	47.15	47.15	53.53	43.02	53.53
Mean	15.31	13.71	15.08	14.97	15.53	15.61
Std. Deviation	11.47	10.90	11.72	11.98	11.43	12.00

[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 product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6
Number of values[a]	20	37	33	32	34	34
Minimum	5.10	1.64	1.64	1.64	1.64	1.64
25th percentile	8.10	8.40	7.30	6.96	6.26	6.72
Median	12.65	17.00	19.78	17.50	13.22	15.17
75th percentile	27.40	29.69	31.89	29.84	23.42	23.14
Maximum	44.40	47.90	47.90	47.90	47.90	44.79
Mean	17.38	20.24	20.99	20.00	16.84	16.90
Std. Deviation	11.57	13.27	13.55	13.00	12.59	11.78

[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	Round 6
Number of values[a]	77	98	99	97	98	99
Minimum	0.00	0.00	0.00	0.00	0.00	0.00
25th percentile	0.84	0.74	0.67	0.64	0.52	0.44
Median	1.58	1.49	1.40	1.25	1.17	1.18
75th percentile	2.25	2.25	2.23	2.25	2.07	2.02
Maximum	9.90	9.90	9.90	9.08	7.74	9.08
Mean	1.93	1.79	1.76	1.72	1.52	1.50
Std. Deviation	1.73	1.66	1.69	1.68	1.52	1.61

[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	Round 6
Number of values[a]	20	40	34	33	35	35
Minimum	3.21	1.70	1.70	1.70	3.21	1.70
25th percentile	4.02	4.11	4.07	4.41	5.55	4.94
Median	6.33	6.15	6.10	6.16	6.86	6.54
75th percentile	8.47	8.47	8.32	9.10	9.43	9.68
Maximum	13.15	13.40	13.30	15.00	15.00	15.08
Mean	6.73	6.81	6.45	6.86	7.78	7.74
Std. Deviation	2.89	3.15	2.90	3.23	3.30	3.69

[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

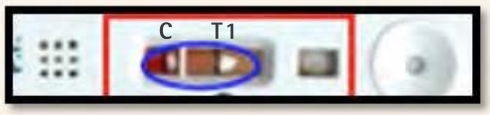
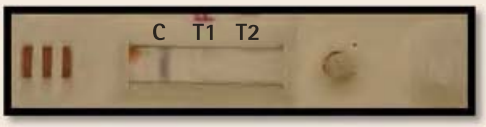
Date of assessment				
Commercial name				
Product code				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed package				
The correctly indicated number of RDTs are in the box				
Desiccant is included in each individual RDT package				
An expiry date is visible on each RDT package				
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 package 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 vial				
The buffer bottle or vial have sufficient volume for testing all RDTs in the box				
The buffer bottle or vial 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)				

NA, not applicable

Figure AS2.1 illustrates examples of RDT observations/anomalies encountered and routinely recorded during round 6 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.

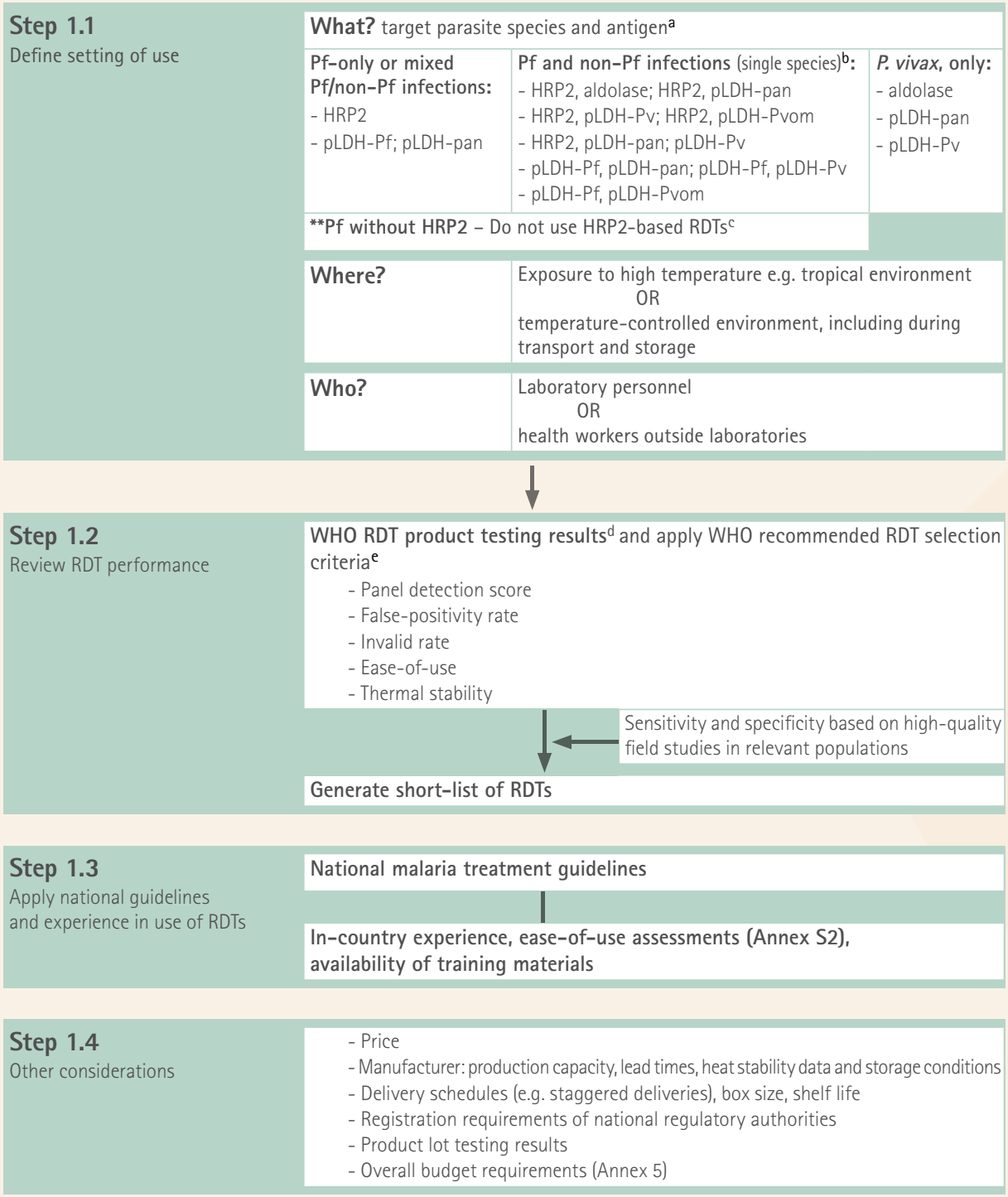
Figure AS2.1: Malaria RDT anomalies encountered in production lots

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		In this example, the result is positive as the test line is visible. Poor clearing of blood may obscure weak positive test lines, giving false-negative results.
b) Observations of flow problems		
Failed migration		Blood and buffer did not run the length of the strip
Incomplete 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 (shift)		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).
Buffer remains pooled in the buffer well		The buffer is not completely absorbed and this may result in failed migration or incomplete clearing.

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 *(1)*.

[d] See references *(2–6)*.

[e] WHO RDT procurement criteria : http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/ (accessed 29 september 2015).

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 *(7)*.

Annex 1: Characteristics of RDTs evaluated in round 6

Manufacturer	Product	Product code	Plasmodium species targeted (F = *P. falciparum* V = *P. vivax* O = *P. ovale* M = *P. malariae* P = pan; major *Plasmodium* species)	Target antigen[a](s)	Sequence and type of bound antibody[b]				Required volume (µL) of whole blood	Buffer drops	Minimum time to results[d] (min)	Maximum reading time (min)	Protocol group[e] (1–8)	Results Interpretation[f] (type A–J)	Format type[g]	Recommended storage temperature (°Celcius)	Shelf-life (months)
					C[c]	T1	T2	T3									
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf)	G0181/ G0181-ET	F	F(pLDH)/ HRP2	P	F(pLDH)/ HRP2			5	2	20		1	A	A	1-40	24
Advy Chemical Private Limited	EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	20	30	3	C	A	2-40	24
	EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	20	30	3	E	A	2-40	24
	EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	F	HRP2	P	HRP2			5	4	20	30	3	A	A	2-40	24
Atomo Diagnostics PTY Limited	ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	F,P	HRP2, pan(pLDH)	P	HRP2	pan(pLDH)		5	4	15	30	7	D	A	4-30	24
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f/PAN Rapid Card	17012	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	20	20	3	C	A	1-30	24
	BioTracer™ Malaria P.f/P.v Rapid Card	17412	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	20		3	E	A	1-30	24
BioNote, Inc.	BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	F	HRP2	P	HRP2			5	4	20	30	3	A	A	1-40	24
	BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	20	30	3	C	A	1-40	24
Core Technology Co., Ltd.	Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/ B42-22	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	15	20	7	E	A	2-30	24
CTK Biotech, Inc.	OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	F,V	HRP2, V(pLDH)	P	HRP2	V(pLDH)		5	2	30	30	4	F	A	1-40	24
	OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	F,P	HRP2, pan(pLDH)	P	HRP2	pan(pLDH)		5	2	30	30	4	D	A	1-40	24
	OnSite Malaria Pf Ag Rapid Test	R0114C	F	HRP2	P	HRP2			5	2	30	30	4	A	A	1-40	24
Guangzhou Wondfo Biotech Co., Ltd.	One Step Malaria P.f Whole blood Test	W37-C	F	HRP2	P	HRP2			5	4	15	30	7	A	A	4-30	24
	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	7	E	A	4-30	24
	One Step Malaria P.f/Pan Whole Blood Test	W62-C	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	15	30	7	C	A	4-30	24
Hangzhou Biotest Biotech Co., Ltd.	RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	F	HRP2	P	HRP2			10	3	10	20	8	A	A	2-30	24
Hema Diagnostic Systems	Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	F	HRP2	P	HRP2			5	2	20	30	1	A	A	4-45	24
Humasis Co., Ltd.	Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	20	20	3	C	A	1-40	24
	Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	20	20	3	E	A	1-40	24
	Humasis Malaria P.f Antigen Test	ANMPF-7025	F	HRP2	P	HRP2			5	4	20	20	3	A	A	1-40	24
InTec Products, Inc.	Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	3	15	20	6	E	A	2-30	24
Lumiquick Diagnostics, Inc.	QuickProfile™ Malaria Pf/Pv Test	71050	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	3	20		2	E	A	4-30	18
	QuickProfile™ Malaria Pf/Pan Test	71063	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	3	20		2	C	A	4-30	18
Medsource Ozone Biomedicals Pvt. Ltd.	Is It... Malaria Pf/Pv Device	AL030	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	3	20	20	2	C	A	2-30	18
Meril Diagnostics Private Ltd.	Merisscreen Malaria Pf/Pan Ag	MHLRPD-01	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	20	30	3	C	A	2-30	18
	Merisscreen Malaria Pf/Pv Ag	MFLRPD-01	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	20	30	3	E	A	2-30	18
Nantong Egens Biotechnology Co., Ltd.	Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	2	20		1	E	A	2-30	24
Oscar Medicare Pvt. Ltd.	Malaria Antigen Test-Pf	MAG01040	F	HRP2	P	HRP2			5	2	30	30	4	A	A	2-45	24

(continued)

Annex 1: Characteristics of RDTs evaluated in round 6 *(continued)*

Manufacturer	Product	Product code	Plasmodium species targeted (F = *P. falciparum* V = *P. vivax* O = *P. ovale* M = *P. malariae* P = pan; major *Plasmodium* species)	Target antigen[a](s)	Sequence and type of bound antibody[b] C	T1	T2	T3	Required volume (µL) of whole blood	Buffer drops	Minimum time to results[d] (min)	Maximum reading time (min)	Protocol group[e] (1-8)	Results Interpre-tation[f] (type A-J)	Format type[g]	Recom-mended storage tem-perature (°Celcius)	Shelf-life (months)
Premier Medical Corporation Ltd.	First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	F	HRP2	P	HRP2			5	2	20	20	1	A	A	1-40	23
	First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	2	20	20	1	C	A	1-40	23
	First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	2	20	20	1	E	A	1-40	23
RapiGEN Inc.	RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	F	HRP2	P	HRP2			5	4	30	30	5	A	A	1-40	24
	RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	30	30	5	E	A	1-40	24
	RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	4	30	30	5	C	A	1-40	24
Shanghai Kehua Bio-engineering Co., Ltd.	KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	15	30	7	E	A	4-30	24
Standard Diagnostics, Inc.	SD Bioline Malaria Ag P.f/P.v	05FK80/ 05FK83	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	4	15	30	7	E	A	1-40	24
	SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	F	F(pLDH), HRP2	P	F(pLDH)	HRP2		5	4	15	30	7	J	A	1-40	24
	SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	F,V	V(pLDH),F(pLDH), HRP2	P	V(pLDH)	F(pLDH)	HRP2	5	4	15	30	7	K	A	1-40	24
Zephyr Biomedicals	FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	F,V	V(pLDH), HRP2	P	V(pLDH)	HRP2		5	2	20		1	E	A	4-30	24
	Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	F,P	pan(pLDH), HRP2	P	pan(pLDH)	HRP2		5	2	20		1	C	A	4-30	24

[a] pLDH, *plasmodium* lactate dehydrogrenase; HRP2, histidine rich protein 2; V, *P. vivax*; F, *P. falciparum*

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

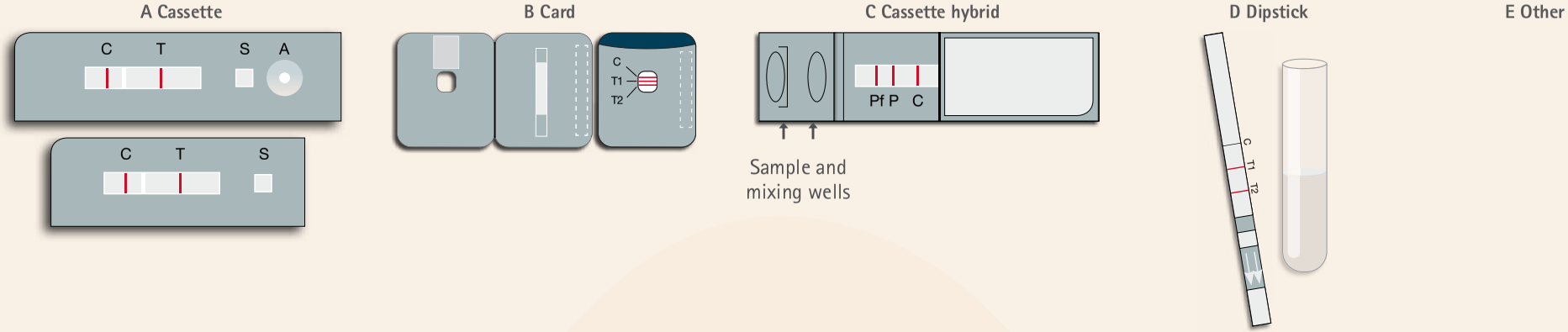
[c] P, present

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

[e] Products have been assigned into different groups based on their procedural characteristics, specifically, blood volume (µL), number of buffer drops and minimum reading time (minutes). The groups are as follows: group 1: 5µL, 2 drops, 20 mins; group 2: 5µL, 3 drops, 20 mins; group 3: 5µL, 4 drops, 20 mins; group 4: 5µL, 2 drops, 30 mins; group 5: 5µL, 4 drops, 30 mins; group 6: 5µL, 3 drops, 15 mins; group 7: 5µL, 4 drops, 15 mins; group 8: 10µL, 3 drops, 10 mins.

[f] See Annex 2

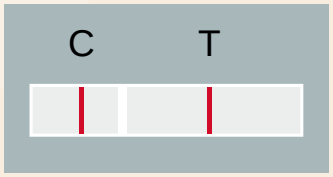
[g] Formats include: cassette (A); card (B); hybrid (C), dipstick (D); or other (E). Each product should ideally be accompanied by all required materials (lancet, pipette, etc.) particularly when used at the village health worker level; however, this is often not the case and the contents depend on the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



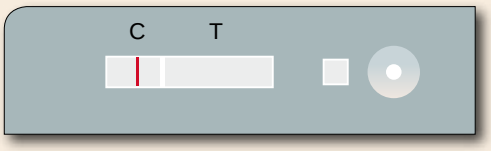
Annex 2: Malaria RDTs: guide to interpretation of results

Type A: Guide to results of generic Pf malaria RDTs

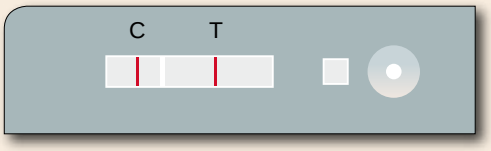
Results window: C=control line; T=test line with bound HRP2 or Pf-specific pLDH antibody.



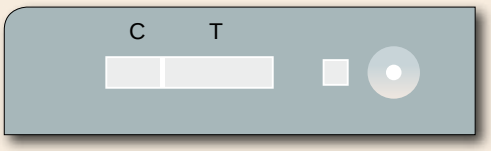
Negative results: One line 'C' appears in the results window.

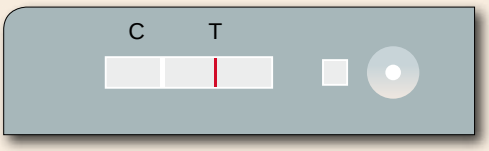


Positive results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window. Test is positive even if the test line is faint.



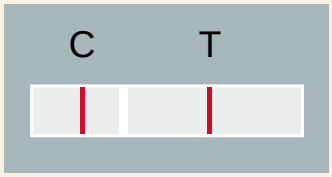
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



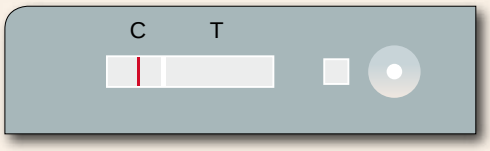


Type B: Guide to results of generic major *Plasmodium* species (pan) malaria RDTs

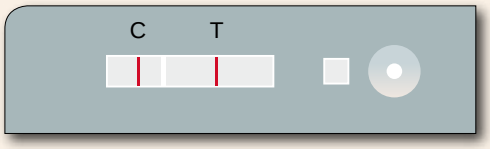
Results window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



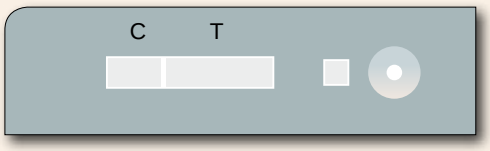
Negative results: One line 'C' appears in the results window.

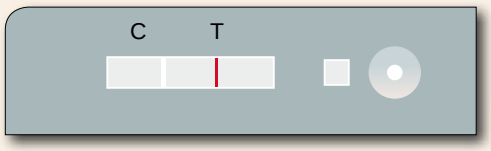


Positive results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



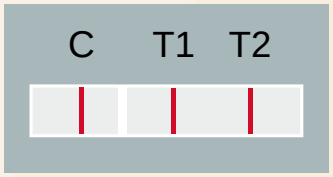
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



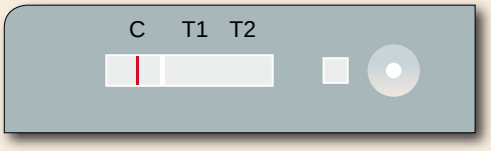


Type C: Guide to results of generic pan-Pf malaria RDTs

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.

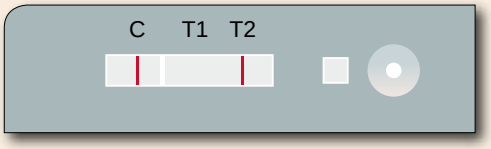


Negative results: Only one line 'C' appears in the results window.

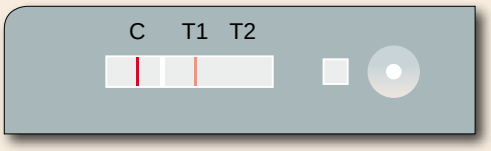


Positive results:

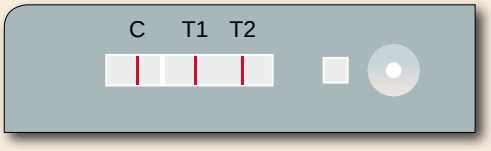
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



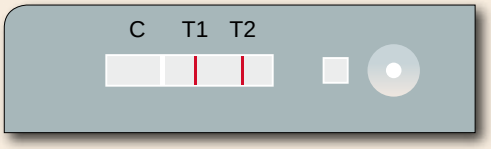
Non-*falciparum* infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection:
Two lines 'C' and 'T1" appear in the results window.

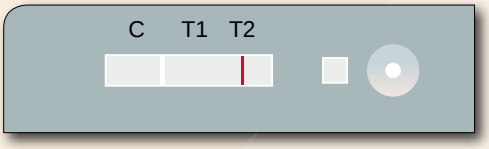


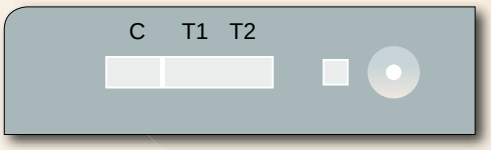
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

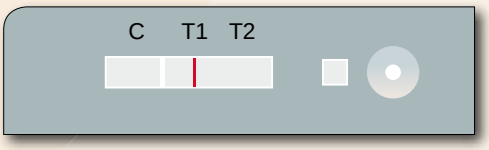


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



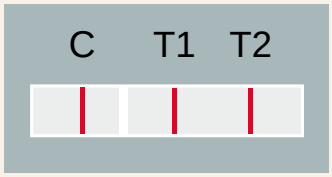




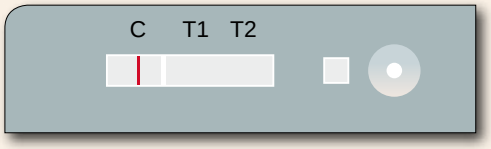


Type D: Guide to results of generic Pf-pan malaria RDTs

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.

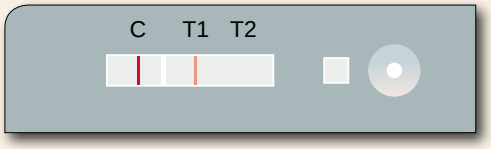


Negative results: Only one line 'C' appears in the results window.

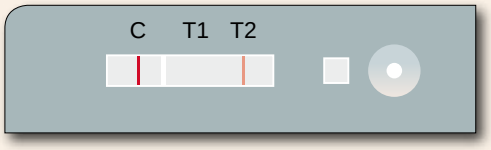


Positive results:

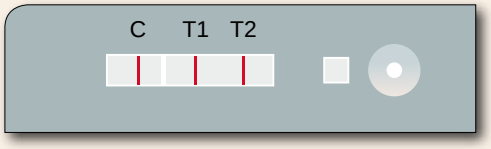
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



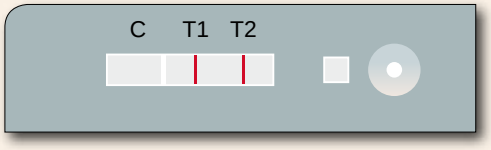
Non-*falciparum* infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection.
Two lines 'C' and 'T2' appear in the results window.

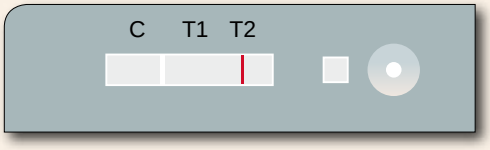


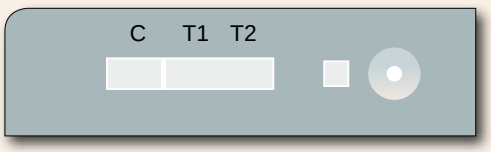
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

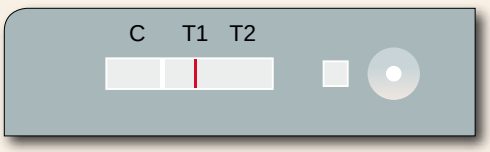


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



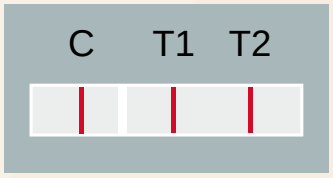




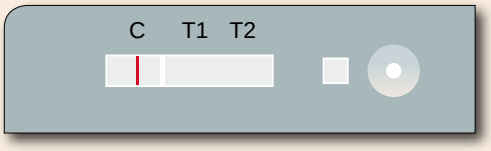


Type E: Guide to results of generic Pv-Pf malaria RDTs

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.

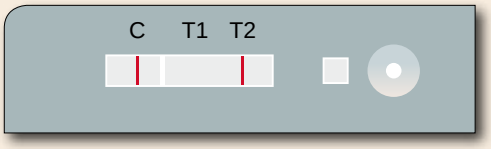


Negative results: Only one line 'C' appears in the results window.

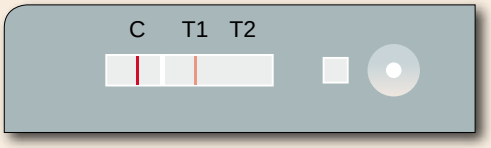


Positive results:

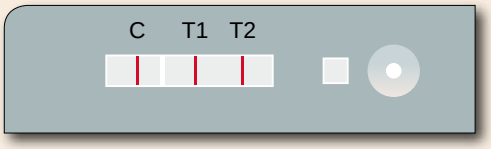
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



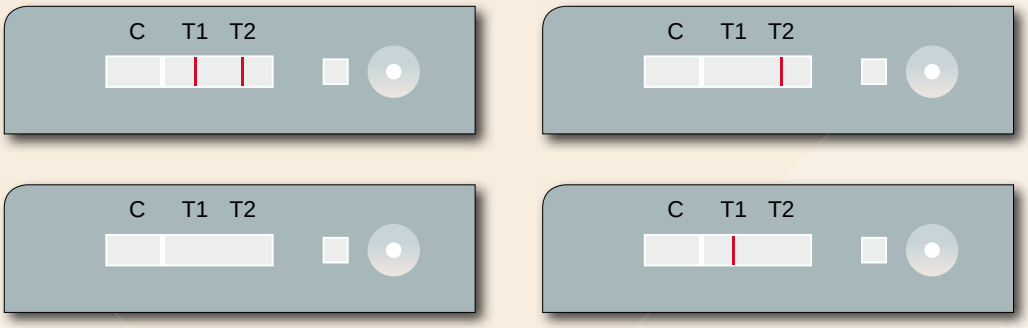
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



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

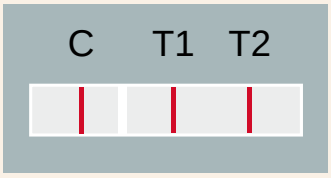


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

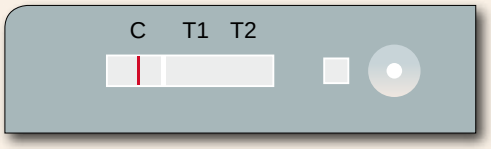


Type F: Guide to results of generic Pf-Pv malaria RDTs

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.

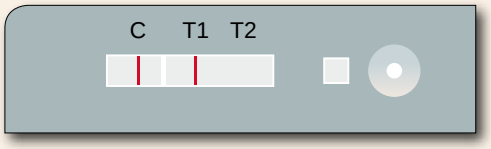


Negative results: Only one line 'C' appears in the results window.

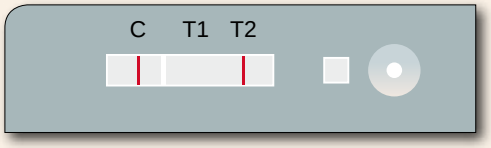


Positive results:

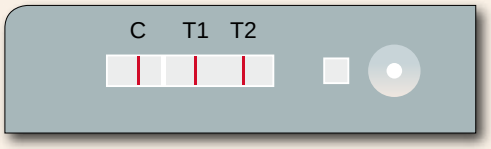
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



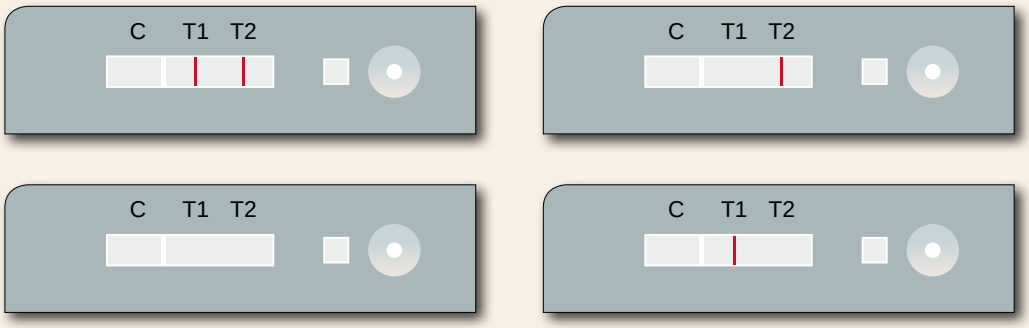
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



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

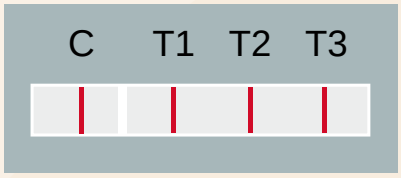


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

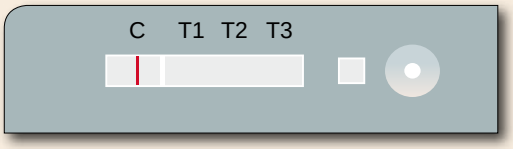


Type G: Guide to results of generic pan-Pv-Pf malaria RDTs

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

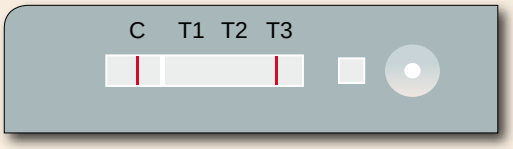


Negative results: Only one line 'C' appears in the results window.

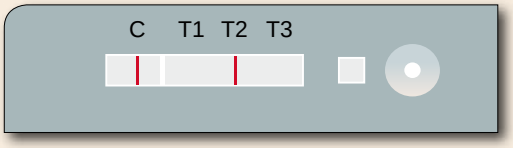


Positive results:

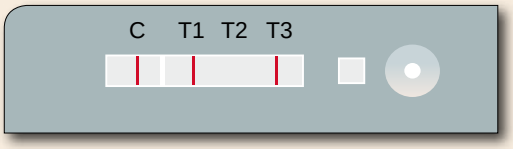
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



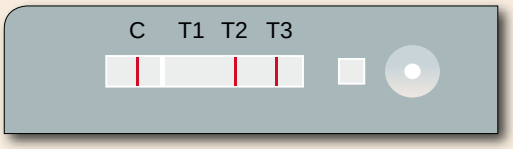
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



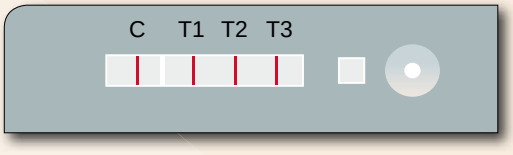
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



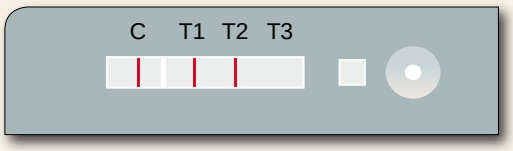
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



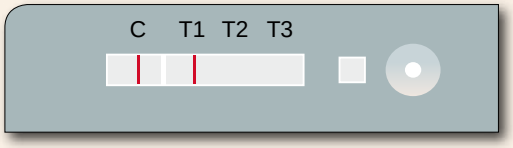
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



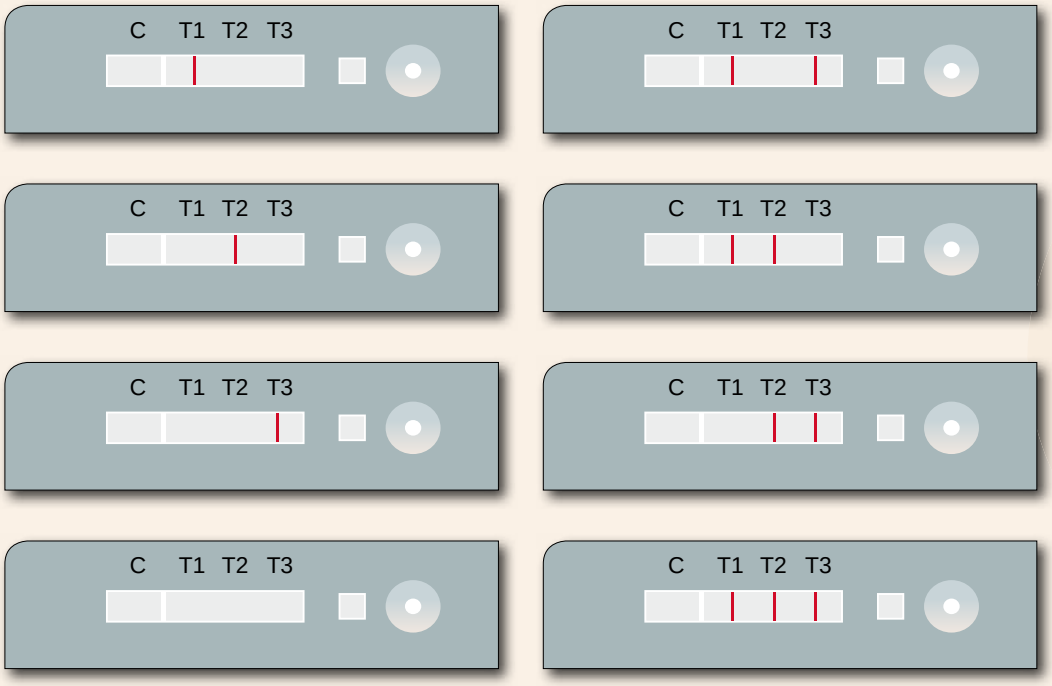
P. vivax **with or without** *P. ovale* **and/or** *P. malariae* **infection. Three lines 'C', 'T1' and 'T2' appear in the results window.**



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

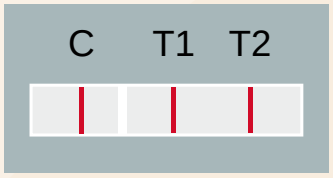


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

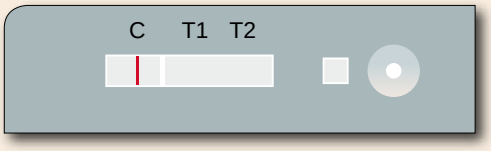


Type H: Guide to results of generic vom[1]-Pf malaria RDTs

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

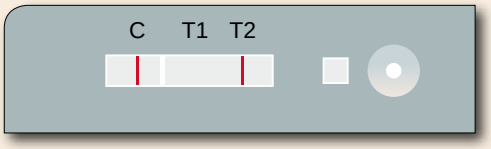


Negative results: Only one line 'C' appears in the results window.

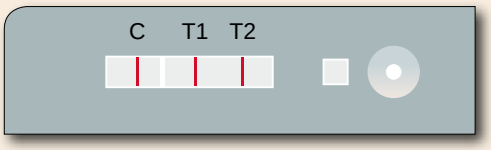


Positive results:

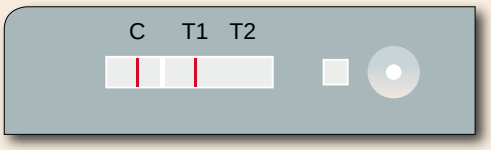
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



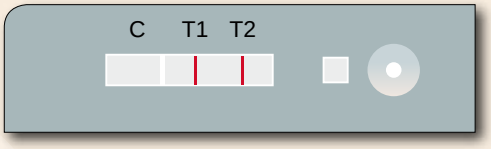
P. falciparum mixed infection (with *P. vivax*, *P. ovale* and/or *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

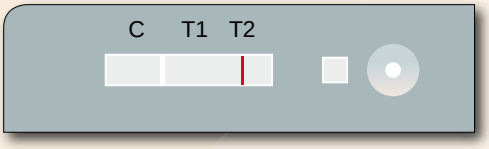


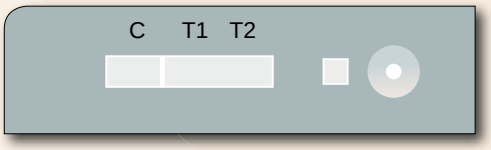
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection. Two lines 'C' and 'T1' appear in the results window.

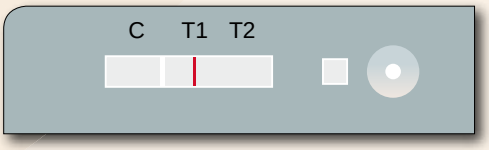


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.





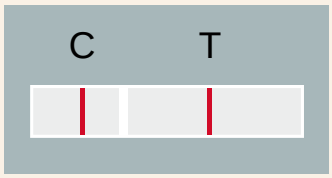




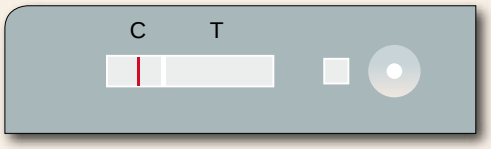
[1] vom, *P. vivax*, *P. ovale*, *P. malariae*

Type I: Guide to results of generic Pv malaria RDTs

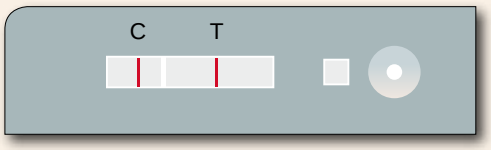
Results window: C=control line; T=test line with bound *P. vivax*-specific pLDH.



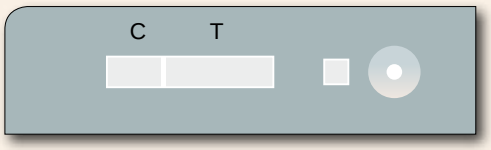
Negative results: Only one line 'C' appears in the results window.

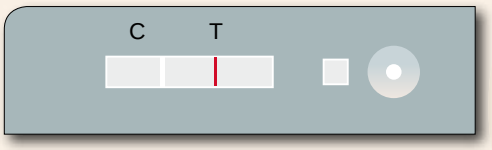


Positive results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



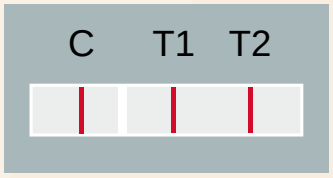
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



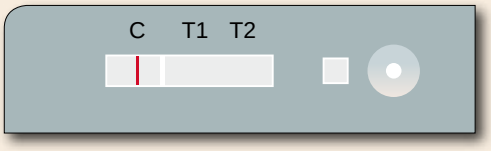


Type J: Guide to results of generic Pf-Pf malaria RDTs

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

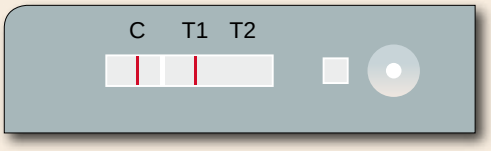


Negative results: Only one line 'C' appears in the results window.

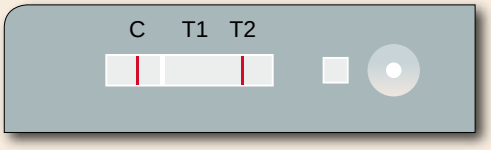


Positive results:

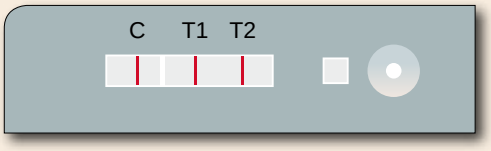
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



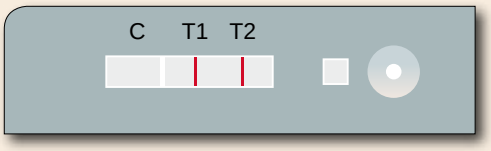
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.

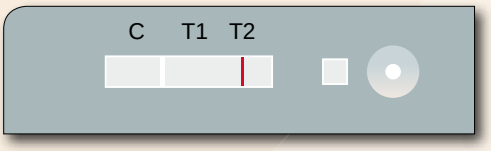


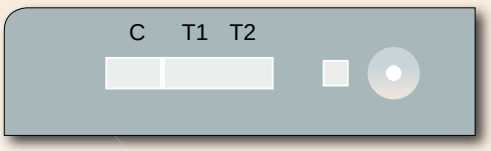
P. falciparum infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

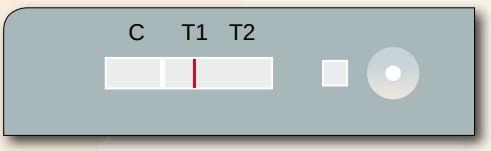


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



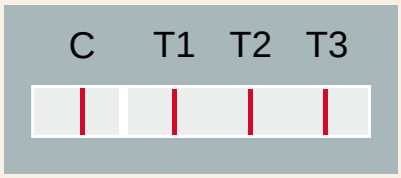




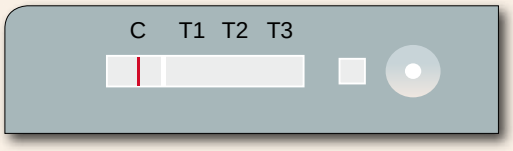


Type K: Guide to results of generic Pv-Pf-Pf malaria RDTs

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).

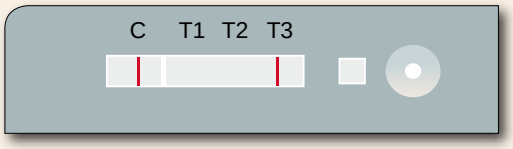


Negative results: Only one line 'C' appears in the results window.

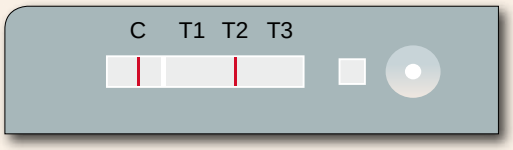


Positive results:

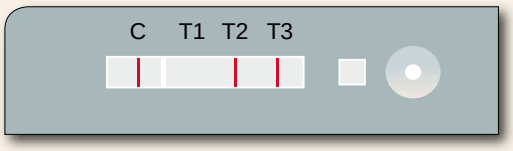
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



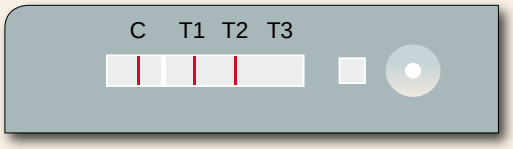
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



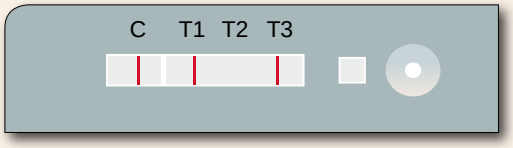
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



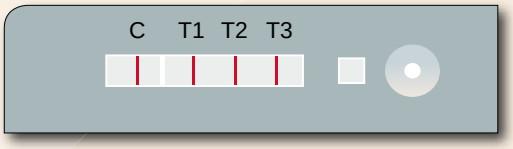
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



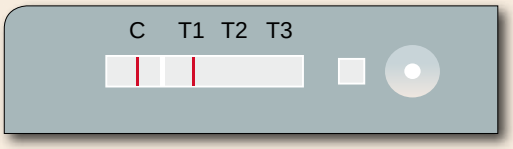
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T3' appear in the results window.



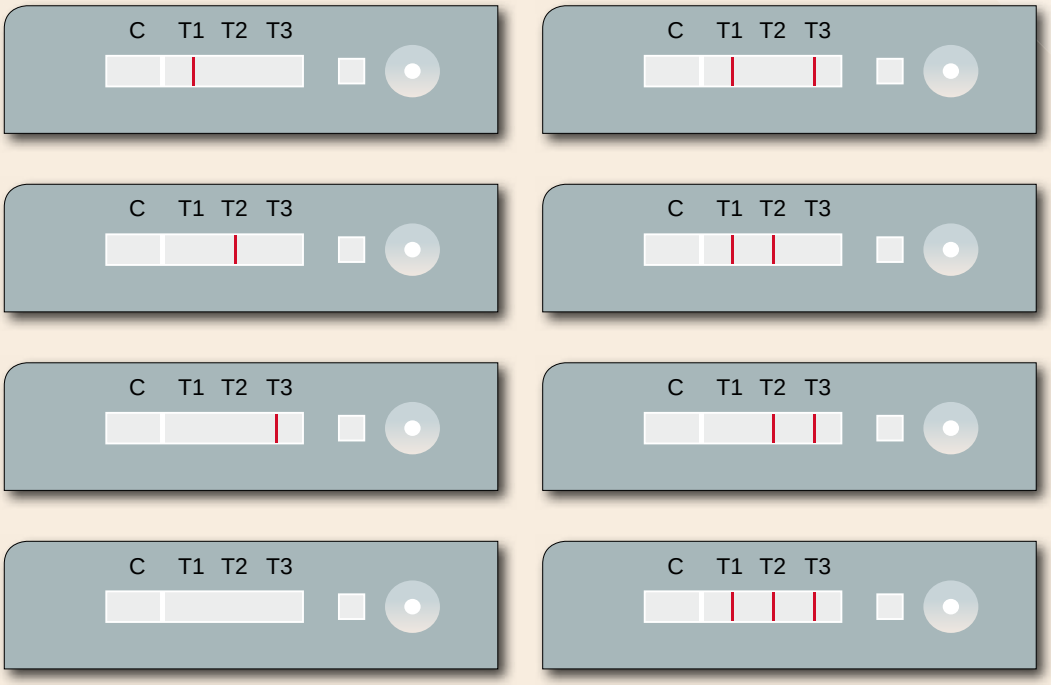
P. falciparum infection and *P. vivax* mixed infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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

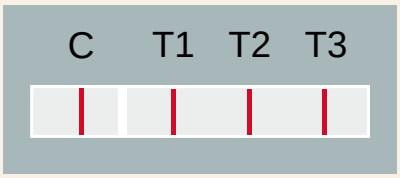


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

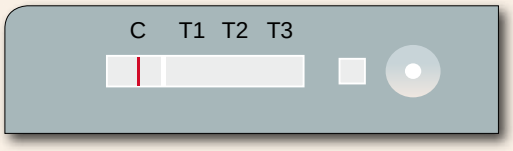


Type L: Guide to results of generic pan-Pf-Pf malaria RDTs

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)

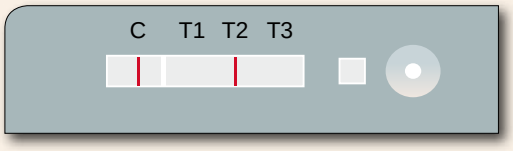


Negative results: Only one line 'C' appears in the results window.

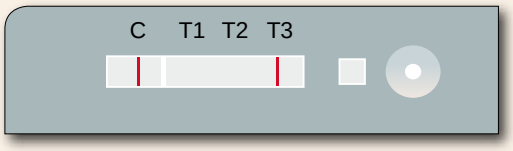


Positive results:

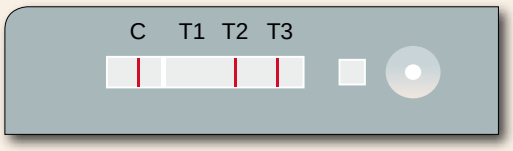
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



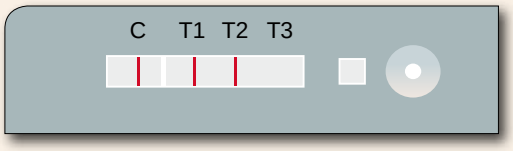
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



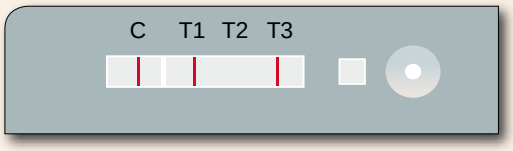
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



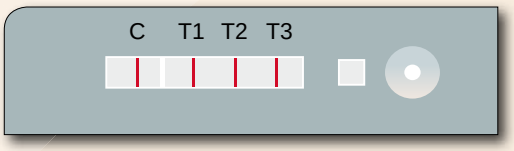
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T2' appear in the results window.



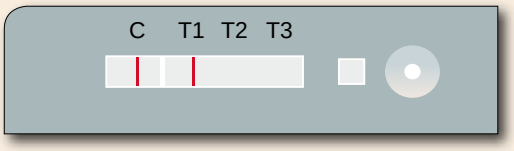
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



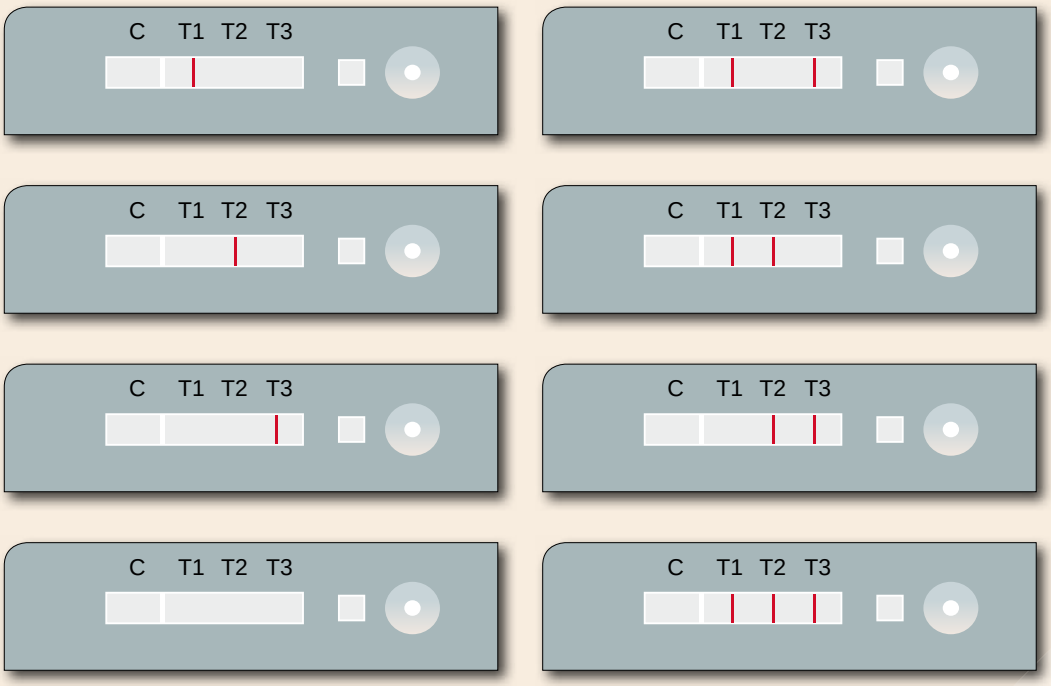
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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

Table A3.1: Lot variability in positive results[a] against phase-1 *P. falciparum* culture samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	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										
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	19.0	19.0	18.0	15.0	15.0	13.0	20.0	20.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	20.0	19.0	19.0	18.0	19.0	17.0	20.0	20.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	19.0	20.0	19.0	18.0	20.0	18.0	20.0	20.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	20.0	20.0	20.0	19.0 (19)	20.0	19.0 (19)	19.0 (19)	20.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Pf and pan										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	18.0	20.0	18.0	20.0	20.0	20.0	20.0	20.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	20.0	20.0	20.0	20.0	19.0	19.0	20.0	20.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	20.0	19.0	19.0	20.0	20.0	20.0	20.0	20.0
OnSite Malaria 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	503030025	Zephyr Biomedicals	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Pf and Pv										
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	20.0	20.0	20.0	19.0	19.0	19.0	20.0	20.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	19.0 (19)	20.0	19.0 (19)	20.0	20.0	20.0	20.0	19.0 (19)

Table A3.1 *(continued)*

Product	Product code	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
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	20.0	20.0	20.0	19.0	18.0	17.0	20.0	20.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	19.0	20.0	19.0	20.0	20.0	20.0	20.0	20.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	20.0	18.0 (19)	18.0 (19)	20.0	20.0	20.0	20.0	20.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	20.0	20.0	20.0	19.0	20.0	19.0	20.0	20.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	20.0	19.0	19.0	19.0	19.0	18.0	20.0	20.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	20.0	20.0	20.0	19.0	20.0	19.0	20.0	20.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	20.0	20.0	20.0	19.0	20.0	19.0	20.0	20.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
Pf and Pf and Pv										
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0

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

[a] Results are based on the first reader's interpretation according to 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	Product code	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																						
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.0	8.8	63.8	25.0	2.5	0.0	0.0	2.5	30.0	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0.0	6.3	47.5	31.3	15.0	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	15.0	61.3	22.5	1.3	0.0	0.0	5.0	35.0	40.0	20.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0.0	15.0	51.3	22.5	11.3	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0.0	38.8	42.5	17.5	1.3	0.0	0.0	5.0	32.5	62.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0.0	3.8	52.5	31.3	12.5	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	5.0	28.8	52.5	13.8	0.0	0.0	0.0	5.0	40.0	55.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	3.8	31.3	40.0	25.0	0.0	0.0	0.0	2.5	40.0	57.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0.0	16.3	58.8	20.0	5.0	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	1.3	3.8	25.0	50.0	20.0	2.5	0.0	0.0	10.0	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	1.3	55.0	36.3	7.5	0.0	0.0	2.5	22.5	40.0	35.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0.0	5.0	37.5	45.0	12.5	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	17.5	82.5	0.0	0.0	0.0	0.0	0.0	82.5	17.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																						
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	18.8	60.0	20.0	1.3	0.0	0.0	5.0	45.0	50.0	100.0	0.0	0.0	0.0	0.0	12.5	85.0	2.5	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	16.3	68.8	15.0	0.0	0.0	0.0	5.0	50.0	45.0	92.5	7.5	0.0	0.0	0.0	0.0	42.5	57.5	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	2.5	3.8	51.3	40.0	2.5	0.0	0.0	2.5	22.5	75.0	28.8	71.3	0.0	0.0	0.0	0.0	0.0	82.5	17.5	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	1.3	47.5	40.0	11.3	0.0	0.0	0.0	15.0	37.5	47.5	80.0	20.0	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	PI16FRC	Premier Medical Corporation Ltd.	0.0	27.5	45.0	20.0	7.5	0.0	0.0	2.5	12.5	85.0	23.8	76.3	0.0	0.0	0.0	0.0	17.5	82.5	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	33.8	43.8	16.3	6.3	0.0	0.0	0.0	27.5	72.5	97.5	2.5	0.0	0.0	0.0	12.5	85.0	2.5	0.0	0.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	1.3	7.5	45.0	31.3	15.0	0.0	0.0	0.0	12.5	87.5	58.8	41.3	0.0	0.0	0.0	0.0	25.0	72.5	2.5	0.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	1.3	42.5	41.3	13.8	1.3	0.0	0.0	5.0	20.0	75.0	36.3	62.5	1.3	0.0	0.0	0.0	15.0	75.0	10.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	1.3	50.0	40.0	8.8	0.0	0.0	0.0	17.5	27.5	55.0	100.0	0.0	0.0	0.0	0.0	55.0	42.5	2.5	0.0	0.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	36.3	43.8	18.8	1.3	0.0	0.0	7.5	42.5	50.0	86.3	13.8	0.0	0.0	0.0	0.0	62.5	37.5	0.0	0.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	22.5	51.3	22.5	3.8	0.0	0.0	0.0	25.0	75.0	50.0	50.0	0.0	0.0	0.0	0.0	2.5	90.0	7.5	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0.0	51.3	41.3	7.5	0.0	0.0	0.0	12.5	47.5	40.0	27.5	72.5	0.0	0.0	0.0	0.0	57.5	42.5	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	0.0	0.0	42.5	38.8	18.8	0.0	0.0	0.0	20.0	80.0	85.0	15.0	0.0	0.0	0.0	0.0	72.5	27.5	0.0	0.0
Pf and Pv																						
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	2.5	48.8	36.3	11.3	1.3	0.0	0.0	7.5	37.5	55.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	30.0	45.0	25.0	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	1.3	47.5	40.0	11.3	0.0	2.5	0.0	15.0	45.0	37.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	3.8	52.5	35.0	7.5	1.3	0.0	5.0	12.5	30.0	52.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	22.5	50.0	17.5	10.0	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	1.3	26.3	42.5	18.8	11.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	1.3	33.8	45.0	15.0	5.0	0.0	0.0	5.0	22.5	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A3.2 *(continued)*

Product	Product code	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
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	13.8	50.0	26.3	10.0	0.0	0.0	2.5	20.0	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	2.5	5.0	61.3	26.3	5.0	0.0	0.0	0.0	20.0	80.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1.3	40.0	43.8	12.5	2.5	0.0	0.0	2.5	35.0	62.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	3.8	45.0	43.8	7.5	0.0	0.0	0.0	17.5	35.0	47.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	1.3	43.8	42.5	12.5	0.0	0.0	0.0	10.0	55.0	35.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	1.3	33.8	50.0	13.8	1.3	0.0	0.0	7.5	37.5	55.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.0	1.3	36.3	46.3	16.3	0.0	0.0	0.0	12.5	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0.0	2.5	50.0	41.3	6.3	0.0	0.0	0.0	22.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pf and Pv																						
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0.0	3.8	40.0	35.0	21.3	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	36.3	63.8	0.0	0.0	0.0	0.0	0.0	67.5	32.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Denotes no 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	Product code	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																		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	93.0	94.0	91.0	92.0	93.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	94.0	95.0	92.0	97.0	97.0	96.0	100.0	99.0	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	79.0	77.0	75.0	78.0	78.0	74.0	100.0	99.0 (99)	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	96.0	95.0	93.0	94.0	96.0	93.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	93.0	91.0	89.0	96.0	95.0	93.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	96.0	97.0	94.0	98.0	96.0	95.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	92.0	92.0	91.0	91.0	93.0	88.0	100.0	99.0	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	83.0 (99)	79.0	78.0 (99)	81.0 (98)	78.0 (99)	73.0 (97)	100.0	99.0	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	96.0	95.0	94.0	98.0	95.0 (99)	95.0 (99)	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	95.0	93.0	93.0	89.0	92.0 (99)	89.0 (99)	98.0 (99)	100.0	NA	NA	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	86.0	88.0	82.0	87.0	86.0	82.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	94.0	95.0	93.0	90.0	94.0	88.0	100.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	95.0	93.0	92.0	93.0 (99)	96.0	93.0 (99)	100.0	100.0	17.0	18.0	12.0	20.0	15.0	14.0	35.0	34.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	89.0	91.0	88.0	86.0	86.0	84.0	100.0	100.0	29.0	30.0	27.0	26.0	28.0	25.0	35.0	35.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	94.0	90.0	89.0	92.0	92.0	88.0	100.0	100.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	88.0	86.0	84.0	83.0	82.0	80.0	100.0	100.0	34.0	33.0	32.0	34.0	35.0	34.0	35.0	35.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	92.0	91.0	87.0	92.0	92.0	89.0	100.0	100.0	35.0	34.0	34.0	35.0	33.0	33.0	35.0	35.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	91.0	95.0	90.0	93.0	93.0	92.0	99.0	100.0	26.0	30.0	25.0	30.0 (34)	31.0	27.0 (34)	35.0	34.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	93.0 (99)	92.0 (97)	87.0 (96)	97.0	95.0 (99)	94.0 (99)	99.0	100.0	34.0	35.0	34.0	34.0	34.0	33.0	34.0 (34)	34.0 (34)
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	86.0	80.0	79.0	88.0	87.0	83.0	100.0	100.0	28.0	28.0	26.0	31.0	31.0	30.0	35.0	35.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	88.0	84.0	81.0	85.0	86.0	83.0	100.0	100.0	11.0	13.0	8.0	19.0	11.0	9.0	35.0	35.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	85.0 (99)	82.0	79.0 (99)	83.0	83.0 (99)	80.0 (99)	100.0	99.0	35.0	32.0	32.0	35.0	33.0	33.0	35.0	34.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	89.0	87.0	85.0	86.0	85.0	81.0	100.0	100.0	34.0	35.0	34.0	35.0	35.0	35.0	35.0	35.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	86.0	84.0	83.0	85.0	85.0	83.0	99.0	99.0 (99)	34.0	35.0	34.0	33.0	35.0	33.0	35.0	35.0

Table A4.1 *(continued)*

Product	Product code	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
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	97.0	96.0	95.0	92.0	93.0 (99)	89.0 (99)	100.0	100.0	34.0	34.0	33.0	35.0	34.0	34.0	33.0	35.0
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	82.0 (98)	80.0 (99)	75.0 (97)	82.0	79.0 (99)	77.0 (99)	100.0	99.0 (99)	25.0	23.0	20.0	25.0	22.0	20.0	34.0 (34)	35.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	95.0	97.0	94.0	94.0	96.0	92.0	100.0	100.0	34.0	34.0	33.0	35.0	35.0	35.0	34.0 (34)	35.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	88.0	88.0	84.0	86.0 (99)	89.0	82.0 (99)	99.0	99.0	30.0	30.0 (34)	28.0 (34)	33.0	33.0 (34)	32.0 (34)	35.0	35.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	87.0	87.0	83.0	81.0	79.0	77.0	100.0	100.0	32.0	32.0	29.0	32.0	34.0	31.0	35.0	35.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	89.0	85.0	84.0	86.0	86.0	82.0	99.0	100.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0	35.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	94.0	92.0	91.0	90.0	91.0	87.0	100.0	99.0 (99)	32.0	32.0	30.0	31.0	33.0	29.0	35.0	35.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	82.0	93.0	91.0	91.0	94.0	91.0	100.0	100.0	34.0	34.0	33.0	33.0	34.0	33.0	35.0	35.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	86.0	95.0	92.0	94.0	96.0	93.0	100.0	100.0	23.0	22.0	19.0	27.0	25.0	22.0	35.0	35.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	95.0 (99)	93.0 (99)	91.0 (98)	94.0 (97)	93.0	89.0 (97)	100.0	98.0 (98)	30.0	28.0	25.0	31.0 (34)	24.0 (33)	22.0 (32)	34.0	35.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	81.0	84.0	78.0	86.0	82.0	81.0	100.0	100.0	21.0	19.0	13.0	24.0	22.0	17.0	35.0	35.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	85.0	86.0	82.0	85.0	85.0 (99)	78.0 (99)	99.0 (100)	100.0	1.0	1.0	0.0	5.0	2.0	1.0	31.0	29.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	79.0	83.0	76.0	81.0	82.0 (99)	79.0 (99)	100.0	98.0	34.0	31.0	31.0	34.0	32.0	31.0	35.0	35.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	87.0	85.0	84.0	85.0	83.0	80.0	100.0	100.0	18.0	22.0	14.0	18.0	17.0	13.0	35.0	35.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	96.0	94.0	94.0	94.0	95.0 (99)	93.0 (99)	100.0	100.0	34.0	35.0	34.0	33.0	35.0	33.0	35.0	35.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	96.0	95.0	95.0	94.0	95.0	92.0	100.0	100.0	33.0	35.0	33.0	35.0	35.0	35.0	35.0	35.0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v[d]	05FK120	Standard Diagnostics, Inc.	90.0	92.0	88.0	87.0	88.0	86.0	100.0	100.0	34.0	35.0	35.0	34.0	34.0	33.0	35.0	35.0

NA, not applicable

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

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

[b] 3 (3%) of the 100 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µL

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

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

Table A4.2: Distribution of test band intensity (0-4) scores against phase-2 wild-type *P. falciparum* samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	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																																
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	7.0	12.8	32.8	32.5	15.0	0.0	0.0	4.0	21.5	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	4.3	13.3	32.0	32.3	18.3	0.5	0.0	2.0	19.5	78.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	22.0	27.3	43.8	6.8	0.3	0.5	1.0	27.5	32.5	38.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	4.8	14.8	33.8	26.5	20.3	0.0	0.0	5.5	20.0	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	6.3	19.0	46.5	23.0	5.3	0.0	0.0	12.0	24.0	64.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	3.3	8.0	34.3	29.8	24.8	0.0	0.0	2.0	19.5	78.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	8.0	17.3	42.5	25.5	6.8	0.5	0.0	9.5	24.5	65.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	19.5	16.3	41.1	20.8	2.2	0.5	1.0	18.5	22.5	57.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	4.0	12.8	28.5	30.0	24.8	0.0	1.0	1.5	14.0	83.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	7.5	8.5	20.8	35.8	27.3	1.0	0.0	2.0	15.5	81.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	13.3	26.8	45.5	13.8	0.8	0.0	1.0	20.0	33.0	46.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	7.0	5.3	28.8	34.3	24.8	0.0	0.0	0.5	14.5	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	28.5	49.0	22.5	0.0	0.0	2.5	0.5	46.0	45.0	6.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																																
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	5.8	13.5	33.8	36.3	10.8	0.0	0.0	2.5	17.0	80.5	76.3	20.3	3.5	0.0	0.0	4.5	25.0	64.0	6.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	12.0	13.5	34.8	34.0	5.8	0.0	0.0	11.0	27.5	61.5	75.0	23.5	1.5	0.0	0.0	4.5	20.0	64.5	11.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	8.0	11.0	38.5	38.0	4.5	0.0	0.0	6.0	44.0	50.0	17.5	59.8	22.5	0.3	0.0	2.0	3.0	53.0	36.5	5.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	15.3	20.5	39.0	21.0	4.3	0.0	0.5	12.5	24.5	62.5	59.8	39.3	1.0	0.0	0.0	3.5	14.0	75.0	7.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	8.3	15.8	29.8	26.0	20.3	0.0	0.0	2.5	17.0	80.5	25.3	63.3	11.5	0.0	0.0	2.5	11.5	59.0	22.5	4.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	7.8	17.8	43.3	24.5	6.8	0.5	0.0	10.5	20.5	68.5	87.8	12.3	0.0	0.0	0.0	12.5	42.0	44.0	1.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	5.8	11.0	24.0	28.5	30.8	0.5	0.5	3.5	11.0	84.5	40.0	45.0	14.8	0.0	0.3	5.5	3.0	70.0	20.0	1.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	14.8	23.3	39.8	19.5	2.8	0.0	1.0	19.0	21.5	58.5	49.3	47.3	3.3	0.3	0.0	10.0	13.5	64.0	11.0	1.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	14.3	21.8	41.5	19.5	3.0	0.0	2.0	14.5	26.0	57.5	94.5	5.3	0.3	0.0	0.0	34.0	38.0	28.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	16.5	18.3	41.6	20.8	2.8	0.5	1.5	19.5	22.5	56.0	74.2	24.6	1.3	0.0	0.0	3.0	26.0	60.5	10.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	13.3	12.5	31.5	34.8	8.0	0.0	0.0	6.0	22.0	72.0	33.3	52.5	14.3	0.0	0.0	2.5	2.5	50.0	35.5	9.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.2 *(continued)*

Product	Product code	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
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	15.0	18.3	44.8	20.0	2.0	0.5	1.0	17.5	25.0	56.0	25.8	62.8	11.5	0.0	0.0	2.0	10.5	74.0	13.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	5.3	9.0	26.6	39.6	19.5	0.0	0.0	2.0	16.5	81.5	63.4	34.8	1.8	0.0	0.0	6.0	24.5	62.5	7.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																																
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	19.3	20.3	40.3	16.3	4.0	0.5	2.5	13.0	25.0	59.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	4.5	10.8	28.8	43.0	13.0	0.0	0.0	1.0	30.5	68.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	12.3	22.0	48.3	15.0	2.5	1.0	0.5	18.5	29.5	50.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	97.3	2.5	0.3	0.0	0.0	99.0	1.0	0.0	0.0	0.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	16.5	20.5	39.8	20.0	3.3	0.0	1.0	14.0	24.0	61.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.8	1.3	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	13.5	11.0	33.0	32.3	10.3	0.5	0.5	7.5	19.5	72.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.5	0.0	0.0	0.0	99.5	0.0	0.0	0.0	0.5
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	8.3	17.0	27.0	27.8	20.0	0.5	0.0	2.5	19.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	7.5	16.3	44.3	23.8	8.3	0.0	0.0	12.0	21.0	67.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.8	0.3	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	4.8	12.0	33.0	33.0	17.3	0.0	0.5	3.0	20.5	76.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.8	0.3	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	6.3	10.5	28.3	42.8	12.3	1.0	0.5	2.0	26.5	70.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	99.5	0.0	0.5	0.0	0.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	16.8	20.3	44.5	15.8	2.8	0.0	1.0	18.5	27.5	53.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.0	2.0	0.0	0.0	0.0	96.0	1.0	2.5	0.5	0.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	14.8	20.8	44.8	18.0	1.8	0.5	1.0	13.0	29.0	56.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	94.5	3.5	2.0	0.0	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	18.5	20.1	41.1	19.5	0.8	1.0	1.5	17.0	29.0	51.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	15.0	16.8	41.5	22.5	4.3	0.0	1.5	13.5	28.0	57.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	96.0	3.0	1.0	0.0	0.0	96.0	0.0	3.5	0.5	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	5.0	8.5	27.1	37.8	21.6	0.0	0.0	1.5	16.0	82.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	97.5	2.5	0.0	0.0	0.0	99.0	0.5	0.5	0.0	0.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	5.0	10.8	31.3	38.3	14.8	0.0	0.0	2.0	23.0	75.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.3	0.3	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Pf and Pf and Pv																																
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 and Pv band	05FK120	Standard Diagnostics, Inc.	11.0	7.3	26.3	36.3	19.3	0.0	0.0	2.0	17.0	81.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	43.3	40.3	16.5	0.0	0.0	2.0	1.5	43.0	46.5	7.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Denotes no visible band

[b] 3 (3%) of the 100 *P. falciparum* dilution samples sets were 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	Product code	Manufacturer	200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL				
			Percentage distribution of Pf test band intensity[b] (n=140)					Percentage distribution of Pf test band intensity[b] (n=70)					Percentage distribution of pan test band intensity[b] (n=140)					Percentage distribution of pan test band intensity[b] (n=70)					Percentage distribution of Pv test band intensity[b] (n=140)					Percentage distribution of Pv test band intensity[b] (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	0[a]	1	2	3	4	0[a]	1	2	3	4
Pf only																																
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181	Access Bio, Inc.	98.6	1.4	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	98.6	1.4	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	98.6	1.4	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	98.6	1.4	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	100.0	0.0	0.0	0.0	0.0	98.6	0.0	1.4	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	97.1	2.9	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	99.3	0.0	0.0	0.7	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	99.3	0.0	0.7	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf pLDH band	05FK90	Standard Diagnostics, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																																
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	97.1	2.9	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	47.9	42.9	9.3	0.0	0.0	1.4	0.0	57.1	31.4	10.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	19.3	51.4	29.3	0.0	0.0	0.0	0.0	28.6	55.7	15.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	9.3	84.3	6.4	0.0	0.0	0.0	1.4	30.0	68.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	2.9	48.6	47.9	0.7	0.0	0.0	0.0	20.0	54.3	25.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag. pLDH/ HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	2.1	21.4	67.1	9.3	0.0	0.0	1.4	8.6	30.0	60.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	99.3	0.7	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	15.7	67.9	16.4	0.0	0.0	0.0	0.0	52.9	38.6	8.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	2.1	10.0	76.4	11.4	0.0	2.9	0.0	4.3	34.3	58.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	15.7	67.9	16.4	0.0	0.0	0.0	1.4	47.1	44.3	7.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	61.4	37.9	0.7	0.0	0.0	0.0	11.4	64.3	24.3	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	100.0	0.0	0.0	0.0	0.0	98.6	0.0	1.4	0.0	0.0	3.6	62.1	34.3	0.0	0.0	0.0	1.4	22.9	54.3	21.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A4.3 *(continued)*

Product	Product code	Manufacturer	200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL				
			Percentage distribution of Pf test band intensity[b] (n=140)					Percentage distribution of Pf test band intensity[b] (n=70)					Percentage distribution of pan test band intensity[b] (n=140)					Percentage distribution of pan test band intensity[b] (n=70)					Percentage distribution of Pv test band intensity[b] (n=140)					Percentage distribution of Pv test band intensity[b] (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	0[a]	1	2	3	4	0[a]	1	2	3	4
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.7	5.0	78.6	12.1	3.6	0.0	0.0	0.0	21.4	78.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	98.6	1.4	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.7	24.3	72.9	2.1	0.0	0.0	0.0	7.1	51.4	41.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	100.0	0.0	0.0	0.0	0.0	97.1	2.9	0.0	0.0	0.0	2.1	57.1	40.7	0.0	0.0	0.0	0.0	30.0	48.6	21.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																																
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	32.1	57.1	10.7	0.0	0.0	1.4	7.1	42.9	32.9	15.7
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.4	57.1	41.4	0.0	0.0	1.4	0.0	12.9	67.1	18.6
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	10.0	61.4	28.6	0.0	0.0	0.0	0.0	20.0	57.1	22.9
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	98.6	1.4	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.1	75.7	17.1	0.0	0.0	0.0	0.0	47.1	40.0	12.9
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	7.1	75.0	16.4	1.4	0.0	0.0	0.0	22.9	77.1
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	8.6	50.7	40.7	0.0	0.0	0.0	0.0	21.4	42.9	35.7
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	3.6	54.3	40.7	1.4	0.0	0.0	0.0	17.1	57.1	25.7
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	30.7	52.1	17.1	0.0	0.0	0.0	0.0	60.0	34.3	5.7
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	19.3	45.0	35.7	0.0	0.0	1.4	0.0	42.9	44.3	11.4
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	38.6	57.9	3.6	0.0	0.0	0.0	8.6	75.7	15.7	0.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	93.6	6.4	0.0	0.0	0.0	14.3	48.6	34.3	2.9	0.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	98.6	1.4	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	6.4	67.9	25.7	0.0	0.0	0.0	0.0	32.9	51.4	15.7
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	46.4	47.9	5.7	0.0	0.0	0.0	1.4	78.6	20.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	100.0	0.0	0.0	0.0	0.0	97.1	2.9	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.1	50.7	46.4	0.7	0.0	0.0	0.0	30.0	38.6	31.4
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.4	10.0	75.0	13.6	0.0	0.0	0.0	2.9	22.9	74.3
Pf and Pf and Pv																																
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.1	15.0	72.9	10.0	0.0	0.0	0.0	0.0	27.1	72.9

NA, not applicable

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

[a] Denotes no visible band

[b] Calculations include invalid tests

Table A4.4: 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	Product code	Manufacturer	*P. vivax* samples (n=35)					
			200 parasites/µL False positive Pf infection[a] (%)			2000 parasites/µL False positive Pf infection[a] (%)		
			Lot 1 (n=70)	Lot 2 (n=70)	Overall (n=140)	Lot 1 (n=35)	Lot 2 (n=35)	Overall (n=70)
Pf only								
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	1.4	0.0	0.7	0.0	0.0	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	2.9	0.0	1.4	0.0	2.9	1.4
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	2.9	0.0	1.4	0.0	2.9	1.4
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	1.4	1.4	1.4	2.9	0.0	1.4
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	4.3	1.4 (69)	2.9 (139)	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	1.4	0.0	0.7	0.0	0.0	0.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	1.4	0.0	0.7	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan								
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	2.9	2.9	2.9	0.0	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	1.4	0.0 (69)	0.7 (139)	0.0	2.9	1.4
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0.0	0.0	0.0	0.0 (34)	0.0 (34)	0.0 (68)
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria 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	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	1.4	1.4	1.4	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	0.0	0.0	0.0	5.7	0.0	2.9
Pf and Pv								
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0	0.0	0.0	0.0 (34)	0.0	0.0 (69)
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0 (34)	0.0	0.0 (69)
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0.0 (69)	0.0 (69)	0.0 (138)	0.0	0.0	0.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0.0	2.9	1.4	0.0	2.9	1.4
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.4 *(continued)*

Product	Product code	Manufacturer	*P. vivax* samples (n=35)					
			200 parasites/µL False positive Pf infection[a] (%)			2000 parasites/µL False positive Pf infection[a] (%)		
			Lot 1 (n=70)	Lot 2 (n=70)	Overall (n=140)	Lot 1 (n=35)	Lot 2 (n=35)	Overall (n=70)
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	1.4	0.0	0.7	0.0	0.0	0.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0 (67)	0.0 (137)	0.0	0.0	0.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	1.4	1.4	1.4	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.0	0.0	0.0	5.7	0.0	2.9
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0.0	1.4	0.7	0.0	0.0	0.0
Pf and Pf and Pv								
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0

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

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

Table A4.5: Phase 2 pan (or *P. vivax*) 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	Product code	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								
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	NA	NA	NA	NA	NA	NA
Pf and pan								
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	0.0 (199)	0.0 (399)	0.0	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	3.0	5.0	4.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	0.0	0.5	0.3	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	1.5	1.5	1.5	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	1.0 (196)	0.0 (199)	0.5 (395)	0.0	0.0	0.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	1.5	1.0	1.3	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0 (199)	0.0 (199)	0.0 (398)	0.0	1.0	0.5
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.5	4.0	2.3	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	5.0	8.0	3.5	1.0	0.0 (99)	0.5 (199)
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	0.0	0.0 (199)	0.0 (399)	0.0	0.0	0.0
Pf and Pv								
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0 (197)	0.0 (199)	0.0 (396)	0.0	0.0 (99)	0.0 (199)
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	3.0	2.5 (199)	2.8 (399)	1.0	1.0	1.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0.0	2.5	1.3	0.0	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.5	0.5	0.5	1.0	0.0	0.5
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0 (99)	0.0 (199)
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0.5	0.0	0.3	0.0	0.0	0.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.5	0.0	0.3	0.0	0.0	0.0

Table A4.5 *(continued)*

Product	Product code	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)
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0.0 (198)	0.0 (197)	0.0 (395)	1.0	0.0 (98)	0.5 (198)
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	4.0	0.0	2.0	8.0	0.0	4.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0 (199)	0.0 (399)	11.0	0.0	5.5
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0 (199)	0.0 (399)	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	7.5	0.5	4.0	7.0	1.0	4.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	4.5	0.5 (199)	2.5 (399)	2.0	0.0	1.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	1.0	0.0	0.5	0.0	0.0	0.0
Pf and Pf and Pv								
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	1.0	0.5

NA, not applicable

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

[a] 3 (3%) of the 100 *P. falciparum* dilution samples sets were 200 and 5000 parasites/µL

Table A4.6: Phase 2 false-positive rate for *P. falciparum* test line results on all malaria-negative samples

Product	Product code	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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=38)	Lot 2 (n=38)	Overall (n=76)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.0	1.0	0.5	0.0	0.0	0.0	3.4	1.7	2.6
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0.0	0.0	0.0	5.3	0.0	2.6	1.7	1.7	1.7
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	1.9	0.0	1.0	2.6	7.9	5.3	3.4	3.4	3.4
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0.0	1.9	1.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	1.0	1.9	1.4	0.0	5.3	2.6	5.2	8.6	6.9
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	1.9	0.0	1.0	2.6	0.0	1.3	0.0	1.7	0.9
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	6.9	6.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0.0	0.0	0.0	2.6	0.0	1.3	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0.0	1.0 (103)	0.5 (207)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	1.7	3.4	2.6
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	2.6	1.3	5.2	6.9	6.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan											
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	0.0 (103)	0.0 (207)	0.0	0.0	0.0	6.9	3.4	5.2
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	1.0	0.5	0.0	2.6	1.3	3.4	3.4	3.4
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	2.6	1.3	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	1.9	1.0	1.4	0.0	2.6	1.3	0.0	1.7	0.9
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0.0	1.0 (103)	0.5 (207)	2.6	0.0	1.3	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	1.0	0.5	0.0	5.3	2.6	3.4	5.2	4.3
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	1.0	0.0 (102)	0.5 (206)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	1.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.9
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0 (103)	0.0	0.0 (207)	0.0	2.6	1.3	0.0	0.0	0.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	1.9	0.0	1.0	0.0	2.6	1.3	3.4	5.2	4.3
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	1.0 (103)	0.0	0.5 (207)	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv											
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0 (103)	0.0	0.0 (207)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	2.6	1.3	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0.0	0.0 (103)	0.0 (207)	5.4 (37)	0.0 (37)	2.7 (74)	3.4	3.4	3.4
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	3.8	1.9	2.9	2.6	0.0	1.3	1.7	25.9	13.8
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1.9	0.0	1.0	0.0	0.0	0.0	0.0	1.7	0.9
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0 (103)	1.0	0.5 (207)	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	1.0 (103)	1.0	1.0 (207)	0.0	2.6	1.3	6.9	3.4	5.2

Table A4.6 *(continued)*

Product	Product code	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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=38)	Lot 2 (n=38)	Overall (n=76)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0.0 (103)	0.0 (100)	0.0 (203)	2.6	0.0	1.3	0.0 (57)	0.0	0.0 (115)
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1.0	1.0	1.0	0.0	0.0	0.0	0.0	1.7	0.9
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0 (103)	0.0 (207)	0.0	0.0 (37)	0.0 (75)	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	3.4	1.8 (57)	2.6 (115)
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.0	0.0 (103)	0.0 (207)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	1.7	3.4	2.6
Pf and Pf and Pv											
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	3.4	5.2	4.3
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

NA, not applicable

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* spp.

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

[b] See Table A4.7 for details

[c] See Table A4.8 for details

Table A4.7: Phase 2 false-positive rate for *P. falciparum* in samples containing specific non-malarial infectious pathogens

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by infectious pathogen							
			Dengue		Schistosomiasis		Leishmaniasis		Chagas	
			Lot 1 (n=12)	Lot 2 (n=12)	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										
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0.0	0.0	16.7	0.0	0.0	0.0	0.0	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	0.0	0.0	8.3	25.0	0.0	0.0	0.0	0.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0.0	16.7	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0.0	0.0	8.3	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	8.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HPR2 band	05FK90	Standard Diagnostics, Inc.	0.0	8.3	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	0.0	0.0	8.3	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	8.3	0.0	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	0.0	0.0	0.0	8.3	0.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0.0	0.0	8.3	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	16.7	0.0	0.0	0.0	0.0	0.0	0.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0	8.3	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0
RapiGEN 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
Pf and Pv										
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	8.3	0.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	16.7	0.0	0.0 (11)	0.0 (11)	0.0	0.0	0.0	0.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0.0	0.0	8.3	0.0	0.0	0.0	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0.0	8.3	0.0	0.0	0.0	0.0	0.0	0.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.7 *(continued)*

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by infectious pathogen							
			Dengue		Schistosomiasis		Leishmaniasis		Chagas	
			Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)	Lot 1 (n=4)	Lot 2 (n=4)
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	8.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0 (3)
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pf and Pv										
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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

Table A4.8: Phase 2 false-positive rate for *P. falciparum* in samples containing potentially cross-reacting blood immunological factors

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by blood immunological factor							
			Rheumatoid factor		Anti-nuclear antibodies		Anti-mouse antibodies		Rapid plasma reagin (RPR) positive	
			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										
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0.0	0.0	0.0	0.0	33.3	16.7	0.0	0.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0.0	0.0	0.0	0.0	16.7	16.7	0.0	0.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	8.3	8.3	0.0	3.9	33.3	33.3	0.0	7.1
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	16.7	0.0	0.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	8.3	16.7	0.0	0.0	33.3	33.3	0.0	0.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0 (25)	0.0	0.0	0.0	0.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0.0	0.0	0.0	0.0	16.7	33.3	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	50.0	66.7	0.0	0.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	0.0	3.9	0.0	50.0	33.3	0.0	0.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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 Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.1
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	7.1
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0.0	0.0 (11)	0.0	0.0	0.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	16.7	0.0	0.0
OnSite Malaria 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
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0.0	8.3	0.0	0.0	33.3	33.3	0.0	0.0
RapiGEN 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
Pf and Pv										
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0	0.0	0.0	0.0 (25)	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0.0	0.0	0.0	0.0	33.3	33.3	0.0	0.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0.0	8.3	0.0	46.2	16.7	33.3	0.0	0.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	7.1
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	8.3	0.0	3.9	0.0	33.3	33.3	0.0	0.0

Table A4.8 *(continued)*

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by blood immunological factor							
			Rheumatoid factor		Anti-nuclear antibodies		Anti-mouse antibodies		Rapid plasma reagin (RPR) positive	
			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)
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0	0.0 (25)	0.0	0.0	0.0	0.0	0.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	3.9	0.0	0.0	0.0	0.0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	0.0 (25)	33.3	16.7	0.0	0.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0.0	0.0 (11)	0.0	0.0	0.0	0.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	16.7	33.3	0.0	0.0
Pf and Pf and Pv										
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	33.3	50.0	0.0	0.0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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

Table A4.9: Phase 2 false-positive rate of pan or *P. vivax* test line results on all malaria-negative samples

Product	Product code	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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=38)	Lot 2 (n=38)	Overall (n=76)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
Pf only											
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	NA	NA	NA	NA	NA	NA	NA	NA	NA
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics, Inc.	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan											
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0.0	0.0 (103)	0.0 (207)	0.0	2.6	1.3	19.0	17.2	18.1
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	2.6	1.3	0.0	0.0	0.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	1.9	1.9 (103)	1.9 (207)	2.6	0.0	1.3	5.2	1.7	3.5
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	1.7	0.0	0.9
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0.0	1.0 (102)	0.5 (206)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0.0	0.0	0.0	0.0	2.6	1.3	0.0	0.0	0.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	3.5	6.9	5.2
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0.0 (103)	0.0	0.0 (207)	0.0	2.6	1.3	1.7	0.0	0.9
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	2.6	1.3	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	8.7	5.8	7.2	18.4	39.5	29.0	56.9	58.6	57.8
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	2.9 (103)	1.9	2.4 (207)	5.3	2.6	4.0	0.0	0.0	0.0
Pf and Pv											
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0.0 (103)	0.0	0.0 (207)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0.0	0.0 (103)	0.0 (207)	0.0 (37)	0.0 (37)	0.0 (74)	10.3	17.2	13.8
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	1.0	2.9	1.9	0.0	0.0	0.0	0.0	17.2	8.6
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	1.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0.0 (103)	0.0	0 (207)	0.0	0.0	0.0	0.0	0.0	0.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0.0 (103)	1.0	0.5 (207)	0.0	0.0	0.0	3.5	3.5	3.5

Table A4.9 *(continued)*

Product	Product code	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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=38)	Lot 2 (n=38)	Overall (n=76)	Lot 1 (n=58)	Lot 2 (n=58)	Overall (n=116)
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	3.5	4.3
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0.0 (103)	0.0 (100)	0.0 (203)	0.0	0.0	0.0	0.0 (57)	0.0	0.0 (115)
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	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 Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	5.2	6.9	6.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0.0	0.0 (103)	0.0 (207)	0.0	0.0 (37)	0.0 (75)	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0.0	0.0	0.0	5.3	0.0	2.6	12.1	1.8 (57)	7.0 (115)
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	3.9	4.9 (103)	4.4 (207)	0.0	0.0	0.0	0.0	0.0 (57)	0.0 (115)
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	2.9	1.0	1.9	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pf and Pv											
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

NA, not applicable

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

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

[b] See Table A4.7 for details

[c] See Table A4.8 for details

Table A4.10: Heat stability testing results for *P. falciparum* test line on a *P. falciparum* sample at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf only																										
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.5	15	0	2.9
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	15	0	3.2	15	0	3.0	14	1	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	1.7	15	0	1.9	15	0	2.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	15	0	3.4	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.2	15	0	3.0	15	0	2.9	15	0	2.9
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	15	0	2.0	15	0	2.0	15	0	2.9	15	0	3.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	3.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	15	0	3.0	15	0	3.3	15	0	3.7	15	0	2.9	15	0	3.1	15	0	3.0	15	0	2.7	15	0	3.1
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	15	0	1.9	15	0	2.0	13	0	2.5	15	0	2.8	15	0	2.0	15	0	2.9	15	0	2.0	15	0	2.9
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	15	0	2.1	15	0	2.6	15	0	2.0	15	0	2.5	15	0	2.2	15	0	2.3	15	0	2.0	15	0	2.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.7	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	15	0	3.0	15	0	3.0	15	0	3.3	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.9	15	0	3.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	13	0	1.0	15	0	1.0	15	0	1.0	12	0	1.0	11	0	1.0	9	0	1.0	15	0	1.0	13	0	1.0
Pf and pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	14	1	2.9	15	0	3.0	15	0	2.9	15	0	3.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.8	15	0	2.7	15	0	3.0	15	0	3.0	15	0	3.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	15	0	3.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	15	0	2.0	15	0	2.1	15	0	2.0	15	0	2.5	15	0	2.0	15	0	2.7	15	0	2.7	15	0	3.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	15	0	3.0	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.6	15	0	2.9	15	0	3.0	15	0	3.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	15	0	2.0	15	0	2.0	15	0	2.9	15	0	2.9	15	0	2.0	15	0	2.2	15	0	2.3	15	0	3.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	15	0	3.1	14	1	3.0	15	0	3.0	14	1	3.1	15	0	3.1	14	0	3.0	15	0	2.9	15	0	3.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.3	15	0	2.0	15	0	2.1
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	15	0	1.8	15	0	1.9	15	0	2.1	15	0	2.4	15	0	2.0	14	0	2.0	15	0	2.1	15	0	2.7
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	15	0	2.0	15	0	2.9	15	0	2.0	15	0	2.5	15	0	2.1	15	0	2.4	15	0	2.2	15	0	2.1
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	15	0	3.0	15	0	2.1	15	0	3.0	15	0	3.0	15	0	2.3	15	0	2.9	15	0	3.0	15	0	2.9
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	15	0	2.0	15	0	2.0	15	0	3.0	15	0	2.7	15	0	2.0	15	0	2.3	15	0	2.1	15	0	2.3
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	14	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0
Pf and Pv																										
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	14	0	2.0	15	0	2.7	15	0	2.3	15	0	2.5	15	0	1.9	15	0	2.1	15	0	2.4	15	0	2.1
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.5	15	0	2.0	15	0	2.3	15	0	2.0	15	0	2.6
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.1	15	0	2.0	15	0	2.7	15	0	2.9	15	0	2.9
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	15	0	3.0	15	0	3.0	15	0	3.0	14	1	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	15	0	3.0	15	0	2.9	15	0	3.0	15	0	2.9	15	0	3.0	14	1	3.0	15	0	2.9	15	0	3.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	15	0	2.0	15	0	2.0	15	0	3.0	15	0	2.9	15	0	2.0	15	0	2.0	15	0	2.0	15	0	3.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	15	0	2.7	15	0	3.0	15	0	3.0	15	0	3.2	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	13	1	3.0	15	0	3.0	14	1	3.0

Table A4.10 *(continued)*

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	15	0	2.0	15	0	2.0	15	0	2.1	15	0	2.0	15	0	2.0	15	0	2.3	15	0	2.0	15	0	2.1
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	15	0	1.9	15	0	2.0	15	0	2.1	15	0	2.5	15	0	1.7	15	0	2.0	15	0	2.1	15	0	2.7
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	15	0	2.0	15	0	2.5	15	0	2.1	15	0	2.6	15	0	2.1	15	0	2.1	15	0	2.1	15	0	2.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	15	0	2.0	15	0	2.0	15	0	3.0	15	0	2.8	15	0	1.9	15	0	1.9	15	0	2.1	15	0	2.4
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	15	0	3.0	14	1	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	15	0	2.8	15	0	3.0	15	0	3.0	15	0	3.0	14	1	3.0	15	0	3.0	15	0	3.0	15	0	3.0
Pf and Pf and Pv																										
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.1	15	0	2.9
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0	0	ND	9	0	1.0	9	0	1.0	0	0	ND	0	0	ND	9	0	1.0	14	0	1.0	9	0	1.0

ND, not determined

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

Table A4.10a: Heat stability testing results for pan test line of combination RDTs on a *P. falciparum* sample at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	ND	0	0	ND	0	0	ND	5	0	1.0	0	1	ND	0	0	ND	0	0	ND	0	0	ND
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	15	0	1.0	15	0	1.0	13	0	1.0	15	0	1.0	15	0	1.1	5	0	1.0	15	0	1.0	12	0	1.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	0	0	ND	1	0	1.0	7	0	1.0	0	0	ND	0	0	ND	3	0	1.0	6	0	1.0	3	0	1.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	15	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0	10	0	1.0	11	0	1.0	12	0	1.0	15	0	1.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	15	0	1.0	12	1	1.0	14	0	1.0	14	1	1.0	11	0	1.0	0	0	ND	8	0	1.0	12	0	1.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	10	0	1.0	4	0	1.0	8	0	1.0	9	0	1.0	0	0	ND	0	0	ND	13	0	1.0	11	0	1.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0	0	ND	0	0	ND	2	0	1.0	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	15	0	1.0	15	0	1.0	12	0	1.0	15	0	1.0	15	0	1.0	13	0	1.0	12	0	1.0	15	0	1.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	15	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	0	0	ND	0	0	ND	3	0	1.0	0	0	ND	3	0	1.0	5	0	1.0	0	0	ND	1	0	1.0

ND, not determined

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

Table A4.11: Heat stability testing results for *P. falciparum* test line on a *P. falciparum* sample at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf only																										
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	5	0	3.0	5	0	3.0	5	0	4.0	5	0	3.8	5	0	3.0	5	0	4.0	5	0	4.0	5	0	4.0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	3.8	5	0	4.0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	3.8	5	0	4.0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	5	0	2.6	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
Pf and Pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	5	0	4.0	4	1	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	5	0	3.8	5	0	4.0	5	0	3.8	5	0	4.0	5	0	3.6	5	0	3.4	5	0	4.0	5	0	4.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Pf and Pv																										
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	4	1	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0

Table A4.11 *(continued)*

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.2	5	0	4.0	5	0	4.0	5	0	4.0
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	5	0	4.0	4	1	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Pf and Pf and Pv																										
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	5	0	1.8	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0

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

Table A4.11a: Heat stability testing results for pan test line of combination RDTs on a *P. falciparum* sample at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)			Lot 1 (n=5)			Lot 2 (n=5)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	5	0	1.0	5	0	1.0	5	0	2.0	5	0	1.2	5	0	1.0	5	0	2.0	5	0	1.0	5	0	2.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.8	5	0	2.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	5	0	2.6	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.8	5	0	2.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	5	0	2.0	5	0	2.2	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.2	5	0	2.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	5	0	1.0	5	0	1.0	5	0	2.0	5	0	1.0	5	0	1.0	5	0	1.4	5	0	1.0	5	0	1.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	5	0	2.0	4	1	2.0	5	0	2.0	5	0	2.0	5	0	1.8	4	0	2.0	5	0	2.0	5	0	2.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	5	0	1.8	5	0	1.8	5	0	2.0	5	0	1.8	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.2
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	4	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	3	0	1.0	4	0	1.0	5	0	1.0	5	0	1.0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	5	0	1.8	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.8	5	0	2.0	5	0	2.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.6	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.6	5	0	2.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.8

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

Table A4.12: Heat stability testing results for *P. falciparum* test line on parasite-negative samples.
Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf only																		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	0	0	2	0	0	0	0	1	1	0	3	0	0	0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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 Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN 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
Pf and Pv																		
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table A4.12 *(continued)*

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table A4.12a: Heat stability testing results for pan or *P. vivax* test line of combination RDTs on parasite-negative samples. Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf and Pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0	0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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 Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0	0	0	0	2	0	3	0	4	0	2	0	0	0	0	0
RapiGEN 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
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table A4.13: Heat stability testing results for *P. falciparum* test line on *P. vivax* samples at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf only																		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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 Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria 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
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN 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
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(continued)

Table A4.13: Heat stability testing results for *P. falciparum* test line on *P. vivax* samples at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C *(continued)*

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0

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

Table A4.14: Heat stability testing results for *P. falciparum* test line on *P. vivax* samples at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf only																		
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria HRP2/pLDH (Pf)	G0181/G0181-ET	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Antigen *P. falciparum* (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f Whole blood Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f (HRP2/pLDH) - Pf-pLDH band	05FK90	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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 Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
OnSite Malaria 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
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN 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
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(continued)

Table A4.14: Heat stability testing results for *P. falciparum* test line on *P. vivax* samples at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C *(continued)*

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.f/P.v - Pf-pLDH band	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table A4.15: Heat stability testing results for *P. vivax* test line on *P. falciparum* samples at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=15)		Lot 2 (n=15)		Lot 1 (n=15)		Lot 2 (n=15)		Lot 1 (n=15)		Lot 2 (n=15)		Lot 1 (n=15)		Lot 2 (n=15)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table A4.16: Heat stability testing results for *P. vivax* test line on *P. falciparum* samples at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing				35 °C				45 °C				Room temperature			
			Lot 1 (n=5)		Lot 2 (n=5)		Lot 1 (n=5)		Lot 2 (n=5)		Lot 1 (n=5)		Lot 2 (n=5)		Lot 1 (n=5)		Lot 2 (n=5)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
Pf and Pv																		
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pf and Pv																		
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

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

Table A4.17: Heat stability testing results for pan or *P. vivax* test line of combination tests on a *P. vivax* sample at low parasite density (200 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=4)			Lot 2 (n=4)			Lot 1 (n=4)			Lot 2 (n=4)			Lot 1 (n=4)			Lot 2 (n=4)			Lot 1 (n=4)			Lot 2 (n=4)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	0	0	ND	3	0	1.0	3	0	1.0	4	0	1.0	4	0	1.0	1	0	1.0	2	0	1.0	3	0	1.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	4	0	1.0	2	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	4	0	1.0	4	0	1.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	4	0	1.8	4	0	2.0	4	0	2.0	4	0	1.5	4	0	1.3	4	0	1.3	4	0	2.0	4	0	1.8
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	4	0	1.8	4	0	2.0	4	0	2.0	4	0	1.5	4	0	1.5	4	0	2.0	4	0	1.3	4	0	1.8
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	2	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	3	0	1.0	3	0	1.0	4	0	1.0	4	0	1.0
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	4	0	1.3	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.0	4	0	2.0	4	0	2.0	4	0	2.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	3	0	1.0	2	0	1.0	4	0	1.0	3	0	1.0	2	0	1.0	0	0	ND	4	0	1.0	4	0	1.0
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1.0	1	0	1.0	0	0	ND	2	0	1.0	0	0	ND	1	0	1.0	0	0	ND	0	0	ND
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.5	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.3
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	4	0	1.3	4	0	1.0	4	0	1.0	4	0	1.3	4	0	2.0	4	0	1.0	4	0	2.0	4	0	1.3
Pf and Pv																										
Advanced Quality™ One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	0	0	ND	2	0	1.0	3	0	1.0	3	0	1.0	4	0	1.0	3	0	1.0	3	0	1.0	3	0	1.0
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.3	4	0	1.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	4	0	1.0	4	0	1.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	4	0	1.0	4	0	1.0	4	0	1.0	1	0	1.0	2	0	1.0	1	0	1.0	4	0	1.0	3	0	1.0
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	4	0	1.0	4	0	1.3	4	0	1.0	4	0	1.5	4	0	1.0	4	0	1.0	4	0	2.0	4	0	1.3
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	3	1	1.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	2	0	1.0	2	0	1.0	4	0	1.0	2	0	1.0	4	0	1.0	2	0	1.0	4	0	1.0	4	0	1.0
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	4	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	2	0	1.0	0	0	ND	4	0	1.0	4	0	1.0
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	1	0	1.0	0	0	ND	2	0	1.0	0	0	ND	0	0	ND	0	0	ND	3	0	1.0	2	0	1.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	3	0	1.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	4	0	1.0	4	0	2.0	4	0	1.3	4	0	2.0	4	0	1.0	4	0	1.8	4	0	1.3	4	0	1.8
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	4	0	1.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8
Pf and Pf and Pv																										
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	4	0	1.0	4	0	1.0	4	0	1.5	3	1	1.3	4	0	2.0	4	0	1.3	4	0	2.0	4	0	1.5

ND, not determined

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

Table A4.18: Heat stability testing results for pan or *P. vivax* test line of combination tests on a *P. vivax* sample at high parasite density (2000 parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Baseline testing						35 °C						45 °C						Room temperature					
			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)			Lot 1 (n=15)			Lot 2 (n=15)		
			No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity	No. positive	No. invalid	Mean band intensity
Pf and Pan																										
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.0	2	0	2.5
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	2	0	2.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	3.0
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	2	0	3.5	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.5	2	0	3.0	2	0	4.0
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	2	0	2.0	2	0	2.0	2	0	3.0	2	0	2.0	2	0	2.0	2	0	2.5	2	0	2.0	2	0	2.5
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	2	0	3.0	2	0	4.0	2	0	3.0	2	0	3.5	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	2	0	2.0	2	0	3.0	2	0	2.0	2	0	2.0	2	0	2.5	2	0	2.0	2	0	2.0	2	0	2.5
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	2	0	1.5	2	0	2.0	2	0	2.0	2	0	2.0	2	0	1.0	2	0	1.5	2	0	1.5	2	0	1.5
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	2	0	2.0	2	0	3.0	2	0	2.5	2	0	2.5	2	0	2.5	2	0	2.5	2	0	3.0	2	0	2.5
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	2	0	3.0	2	0	4.0	2	0	4.0	2	0	4.0	2	0	3.5	2	0	4.0	2	0	4.0	2	0	3.5
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	2.0	2	0	3.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	RapiGEN Inc.	2	0	2.5	2	0	3.0	2	0	2.5	2	0	3.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	2.5
Pf and Pv																										
Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	InTec Products, Inc.	2	0	1.5	2	0	2.5	2	0	2.0	2	0	2.0	2	0	1.5	2	0	2.0	2	0	2.0	2	0	2.5
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	2	0	2.5	2	0	2.5	2	0	3.0	2	0	2.0	2	0	2.5	2	0	2.0	2	0	2.5	2	0	3.0
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	2	0	2.0	2	0	2.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	2.5	2	0	3.0	2	0	3.0
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.5	2	0	2.5
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	2	0	3.0	2	0	4.0	2	0	3.5	2	0	3.5	2	0	4.0	2	0	3.5	2	0	4.0	2	0	3.0
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	2	0	2.0	2	0	2.5	2	0	3.0	2	0	3.5	2	0	2.5	2	0	3.0	2	0	4.0	2	0	3.5
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	2	0	2.0	2	0	2.5	2	0	3.0	2	0	2.5	2	0	2.5	2	0	2.5	2	0	3.0	2	0	3.0
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	2	0	2.0	2	0	2.5	2	0	2.5	2	0	2.5	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.5
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	2	0	2.0	2	0	3.0	2	0	2.5	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.5	2	0	2.5
Meriscreen Malaria Pf/Pv Ag	MFLRPD-01	Meril Diagnostics Private Ltd.	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	1.5	2	0	2.0	2	0	2.0
One Step Malaria P.f/P.v Whole Blood Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	2	0	1.5	2	0	1.0	2	0	1.0	2	0	1.0	2	0	1.0	2	0	1.0	2	0	2.0	2	0	1.5
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	2	0	2.0	2	0	2.5	2	0	3.0	2	0	2.5	2	0	2.0	2	0	3.0	2	0	2.5	2	0	2.0
QuickProfile™ Malaria Pf/Pv Test	71050	Lumiquick Diagnostics, Inc.	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	1.0	2	0	1.0	2	0	1.0	2	0	2.0
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	2	0	3.0	2	0	4.0	2	0	3.5	2	0	4.0	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.5
Pf and Pf and Pv																										
SD Bioline Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics, Inc.	2	0	3.0	2	0	4.0	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0

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

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 (*8*–*9*). 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]

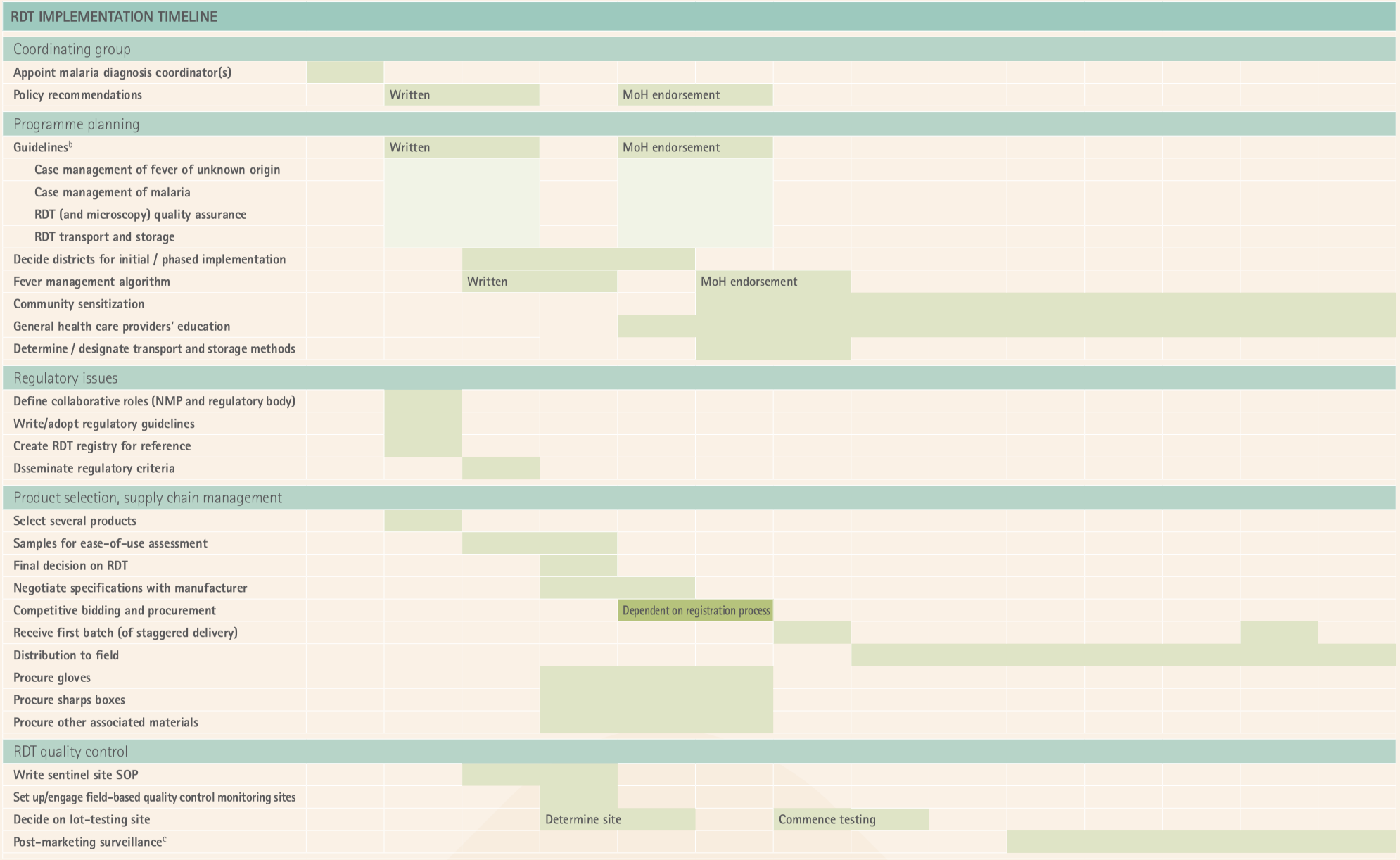
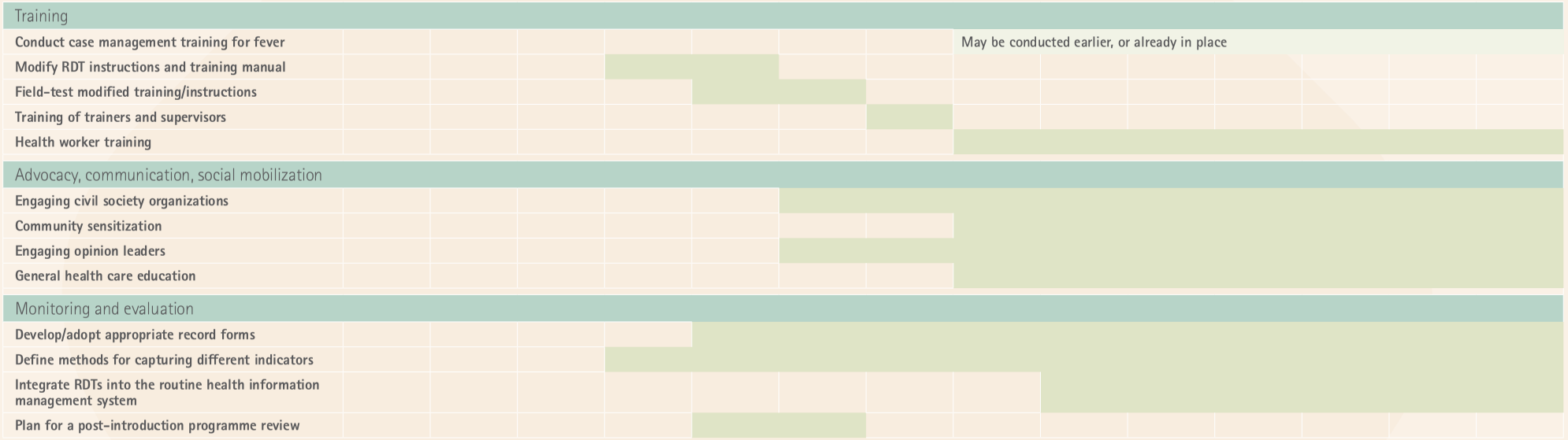


Figure A5.1 *(continued)*



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 microscopy, 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 (*8*)

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

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