Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: round 7 (2015–2016)

World Health Organization

FIND
Because diagnosis matters

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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 WHO prequalification is not currently a requirement for WHO procurement, manufacturers are encouraged to apply for it. 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. The recommendations were established by the WHO Malaria Policy Advisory Committee in 2012, are outlined in this report and are presented in full in a WHO information note (available at *http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf*). Products that do not meet the full set of minimum performance criteria are not eligible for procurement by WHO. As of 1 January 2018, WHO prequalification will become a requirement for procurement recommendation (*http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/*).

The lists of RDTs included in this report are not exhaustive but reflect those products that were submitted for evaluation in rounds 4–7 of the WHO Malaria RDT Product Testing Programme. Their mention indicates the extent to which 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 evaluations indicated in the figures and tables apply only to the specific product listed with its unique product code or catalogue number and as manufactured by the listed company.

Improper storage, transport or handling of malaria RDTs may affect their performance.

The fact that certain products are not included in any of the lists and figures in this report indicates that they have not or not yet been submitted for evaluation to the WHO Malaria RDT Product Testing Programme or that their evaluation has not yet been completed and published or that they have been removed from summary reports due to noncompliance with compulsory resubmission requirements. It does not 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 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 evaluations are published by WHO, WHO cannot ensure that products on the lists and in figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that, before procuring a malaria RDT, each lot of that product be tested at one of the two following lot-testing laboratories: the Institut Pasteur du Cambodge, Cambodia, or the Research Institute for Tropical Medicine, 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-VIII.

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

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ACKNOWLEDGEMENTS

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ABBREVIATIONS

CDC	United States Centers for Disease Control and Prevention
ELISA	enzyme-linked immunosorbent assay
FIND	Foundation for Innovative New Diagnostics
HRP2	histidine-rich protein 2
ISO	International Organization for Standardization
PCR	polymerase chain reaction
PDS	panel detection score
pLDH	*Plasmodium* lactate dehydrogenase
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 1–7

1.1. Introduction

WHO estimates that 3.2 billion people are at risk for malaria. In 2015, there were an estimated 212 million new cases (with an uncertainty range of 148 million to 304 million) and an estimated 429 000 deaths (with an uncertainty range of 235 000 to 639 000). Approximately 90% of these deaths occurred in sub-Saharan Africa and just over 70% were of children under 5 years. Malaria remains endemic in 91 countries and territories and while parasite-based diagnosis is increasing, national surveys between 2013 and 2015 suggest approximately 31% of suspected malaria cases in sub-Saharan Africa were not confirmed with a diagnostic test, 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 non-governmental 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.

WHO's malaria RDT product testing constitutes the laboratory evaluation component of WHO malaria RDT prequalification, but meeting WHO prequalification criteria has not previously been a requirement for a WHO recommendation on procurement. As of 1 January 2018, WHO prequalification, comprising a dossier and inspections of manufacturing sites as well as a laboratory evaluation, will determine the eligibility of malaria RDTs for procurement. Therefore, all manufacturers that submit products to Round 8 and future rounds will be required also to submit applications for WHO prequalification.

RDT sales increased from 46 million in 2008 (before implementation of the product testing programme) to 320 million in 2013 (according to manufacturer sales data). In 2014, the number of diagnostic tests provided (RDTs and microscopy combined) in Africa exceeded the total number of courses of artemisinin-based combination therapy administered in Africa for only the second time. Since 2013, decreasing RDT sales in Asia have led to an overall decrease in global sales (270 million were sold globally in 2015); however, sales in Africa have continued to rise each year since 2008. By 2014, it was confirmed that all 91 countries with ongoing malaria transmission had adopted the WHO policy of testing before administering treatment. Despite these achievements, a large number of cases remain undiagnosed, particularly in the private sector, indicating that some gains are still to be made (*1*).

This summary presents an overview of the results of rounds 4–7 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 7. With the exception of products that are no longer manufactured and/or are de-listed 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 (*3–8*) 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

[1] See full reports of rounds 1–7 for lists of collaborating partners.

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, 41 and 46 products from 13, 23, 27, 34, 22 and 27 manufacturers were evaluated in rounds 2, 3, 4, 5, 6 and 7, respectively. Of these 297 products, 293 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 and 7, specific observations of RDT anomalies were also systematically recorded. Many manufacturers have decided voluntarily to submit products to one or more rounds of testing, and, in round 5, a requirement was instituted to resubmit products for re-evaluation within 5 years of original testing (Table S1). Of the 293 fully evaluated products in rounds 1–7, 31 have been evaluated twice, 21 have been evaluated three times, two evaluated four times and three evaluated five times. Of the 202 unique products tested in the programme, 65 detect *P. falciparum* alone, 143 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 (*9*) 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 1–6.

Of the 30 products due for compulsory retesting in round 7, five were submitted (Table S1). Round 3 products that were not resubmitted have been removed from the figures and tables in this summary performance document.

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. The aim of the evaluation is to provide comparative data on the performance of the submitted production lots of each product. Since 2009, these data have guided procurement decisions by WHO, other United Nations agencies and national governments.

WHO product testing has constituted the laboratory evaluation component of the WHO prequalification process for malaria RDTs (*10*), which additionally includes a standardized dossier review and a manufacturing site inspection to ensure safety, quality and performance comprehensively. WHO prequalification of in vitro diagnostics, established in 2008, is used in all United Nations agencies to determine the eligibility for procurement of tests for HIV, hepatitis B and C and syphilis and by national authorities to complement their national regulatory approvals. WHO prequalification will determine the eligibility of malaria RDTs for procurement as of 1 January 2018[1].

To facilitate this transition, manufacturers with products that currently meet procurement criteria and those submitting to future rounds of lab evaluations are required to submit applications to WHO prequalification. Only those products that meet WHO prequalification requirements by 31 December 2017 will be eligible for WHO procurement. An eigth round of product testing started in February 2017.

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 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 (*11*). 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.

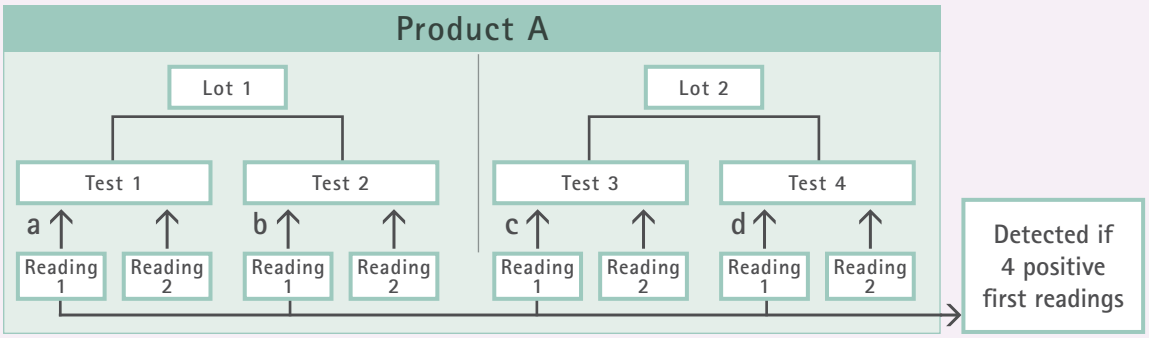
The PDS is the percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or by a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density, 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

[1] http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/

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.

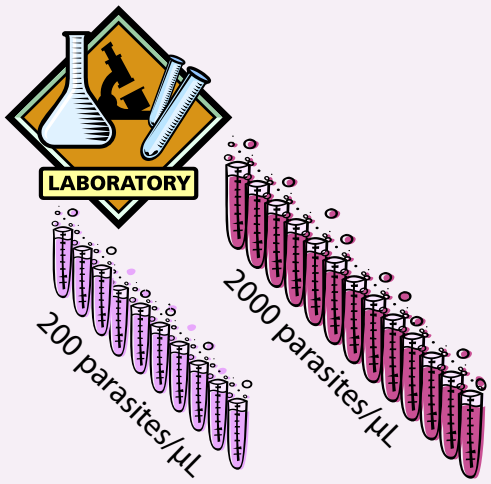
In the above example, the positivity rate is: 9/12 = 75%.

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.

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 (Peru, Colombia, Brazil), India and Africa (Eritrea, Ghana, Rwanda) do not express HRP2 (*12–13* , *33-34*). 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 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.

To encourage manufacturers to meet international standards and best practice in the packaging and labelling of malaria RDTs, with the goal of ensuring better, more consistent ease of use, WHO and partners have made recommendations for the instructions for use and labelling of malaria RDTs (*14*). Evaluation of adherence to the recommendations was introduced in round 7.

Detailed results can be found in the report of each evaluation (*3–8*) and at http://www.who.int/malaria/publications/diagnostic_testing/en/ (accessed 8 March 2017).

1.4. Summary of outcomes

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 7, the proportion of tests that achieved a PDS ≥ 75% at a density of 200 parasites/µL is slightly lower than in round 6 for both *P. falciparum* (87.0%%) and *P. vivax* (70.0%).

Several RDTs in the seven 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) in round 7, all products had a high rate of detection of *P. falciparum* at 2000 parasites/µL (PDS of 100%), as did the majority of products for *P. vivax* at 2000 parasites/µL.

In all except two of the RDTs submitted to round 7, the HRP2 antigen was used to detect *P. falciparum*, either alone (41 products) or with Pf-pLDH (3 products). In the two exceptions, Pf-pLDH was used alone. Of the five products that detected Pf-pLDH, two combined Pf-pLDH with HRP2 in the same test line, one had dual test lines for detecting *P. falciparum* (one HPR2 and one Pf-pLDH test line), and two had only Pf-pLDH. While the dual test line product performed well overall, the line for detecting Pf-pLDH performed considerably less well than the HPR2-detecting test line at 200 µL, with a PDS of 38%. The PDS of the two products with Pf-pLDH alone for detecting *P. falciparum* at 200 parasites/µL were 75% and 73%. Thus, after seven rounds of testing, the choice of well-performing pLDH-based *P. falciparum* tests and of pan-only tests remains limited.

The test performance of lots in round 7 varied only slightly, with an average difference in positivity rates of 1.5 percentage point (range, 0–4.5%) and 1.0 percentage point (range, 0–3.5%) when tested against 200 parasites/µL wildtype *P. falciparum* and *P. vivax*, respectively (Tables A3.1 and A4.1), a pattern also seen in round 6. In previous rounds, however, wide variation was found, indicating the advisability of testing lots after purchase and before use in the field. The frequency of anomalies that can interfere with test interpretation was recorded for the first time in round 6. In round 7, one to five anomalies were found with 33 of the 46 products (Annex S2, Table 8, Fig. 30). Incomplete clearing and a red background were the most common anomalies, seen in 48% and 24% of products, respectively. The next most common anomalies were incomplete migration, failed migration and a red background obscuring the test lines, in 15%, 11% and 11% of products, respectively. Most products (44/46) had anomalies in < 1% of the tests; two products had anomalies in 1.4% of products (Table 8). Overall, fewer types and a lower frequency of anomalies were seen in round 7 than in round 6.

All except one of the RDTs evaluated in round 7 were in cassette format; the exception was in dipstick format.

Only 5 of the 30 RDTs due for compulsory resubmission were submitted for retesting. All met the WHO procurement criteria on initial testing. Two products (one for *P. falciparum* only and one combination RDT) scored higher in re-testing, with percentage point increases of 7 and 6, respectively, in the PDS at 200 µL against *P. falciparum* and an increase of 6 percentage points against *P. vivax* for the combination RDT. Three re-tested products (one *P. falciparum* only, two combination RDTs) scored lower than in their initial testing, with percentage point decreases of 7, 8 and 16 in the PDS at 200 µL against *P. falciparum* and a decrease of 91 percentage points (to a score of zero) in the PDS against *P. vivax* for the combination RDT. Of these three products with diminished performance, two no longer meet the criteria for procurement. Four products showed decreased false-positive rates on re-testing, whereas one had an increase from 0% to 5% at 200 µL.

1.5. De-listing of products in summary report

Products that are due for compulsory resubmission (every 5 years) but are not resubmitted are removed from the summary results listing (Tables S2 and S3) and the online interactive database (*15*) and are featured only in the full round-specific product testing report. They are also not eligible for WHO procurement. Furthermore, a product is de-listed if WHO is notified by the manufacturer that its production has been discontinued. To date, 72 products have been delisted (Table S4).

1.6. How product testing results can inform RDT procurement and use

Accurate diagnosis is vital to good malaria case management, whether based on microscopy or on 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 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 is maintained by FIND (*15*). 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.

The results in the product testing reports are presented by product, which are described by their name and "product code". The same RDT may be sold in a variety of product configurations, such as single or multi-kits, the number of tests per box, with or without certain accessories, and they are assigned a series of distinct product codes on this basis. The reports lists the precise name and product code as provided by the manufacturer for testing. Procurers should contact the manufacturer for a list of product configurations before purchase.

Comprehensive guidance on several aspects of procurement can be found in *Recommended selection criteria for procurement of malaria rapid diagnostic tests (16)*, published as a WHO information note in 2016[2] and *Good practices for selecting and procuring rapid diagnostic tests for malaria* (*16*). Guidance on implementation is provided in *Universal access to malaria diagnosis* (*17*).

[1] The WHO-FIND malaria RDT evaluation programme provides lot-testing capacity in two regional laboratories free of charge. Information on the programme and how to access it can be found at: https://www.finddx.org/malaria-rdt-qa/ (accessed 8 March 2017).

[2] http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf (accessed 3 April)

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.

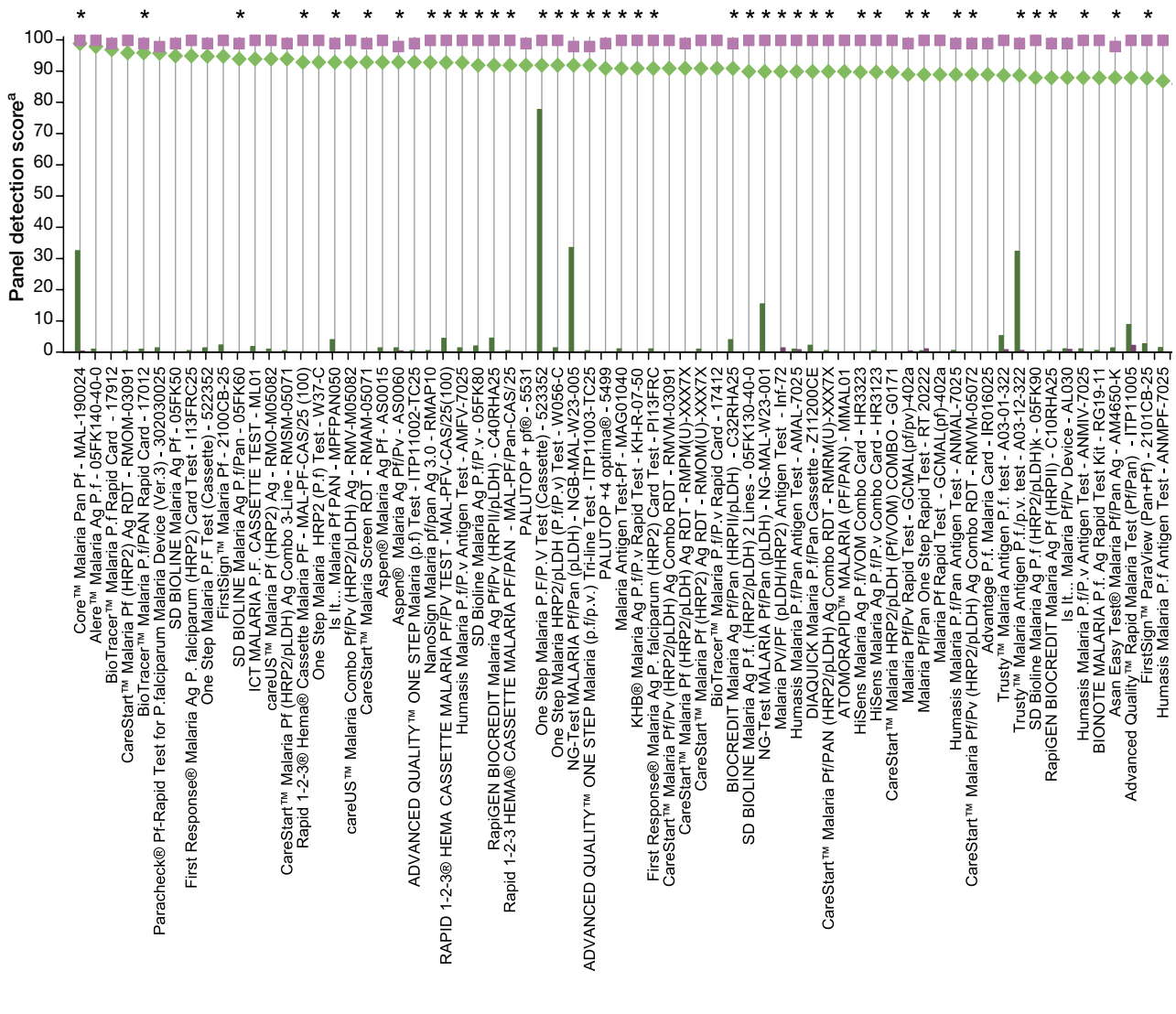
(C) The false positive rate should be less than 10%.

(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

As of 1 January, 2018 WHO procurement recommendations for malaria RDTs will change to require WHO prequalification designation[1].

Figure S1: Malaria RDT performance in phase 2 of rounds 4–7 against wild-type (clinical) samples containing *P. falciparum* at low (200) and high (2000) 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

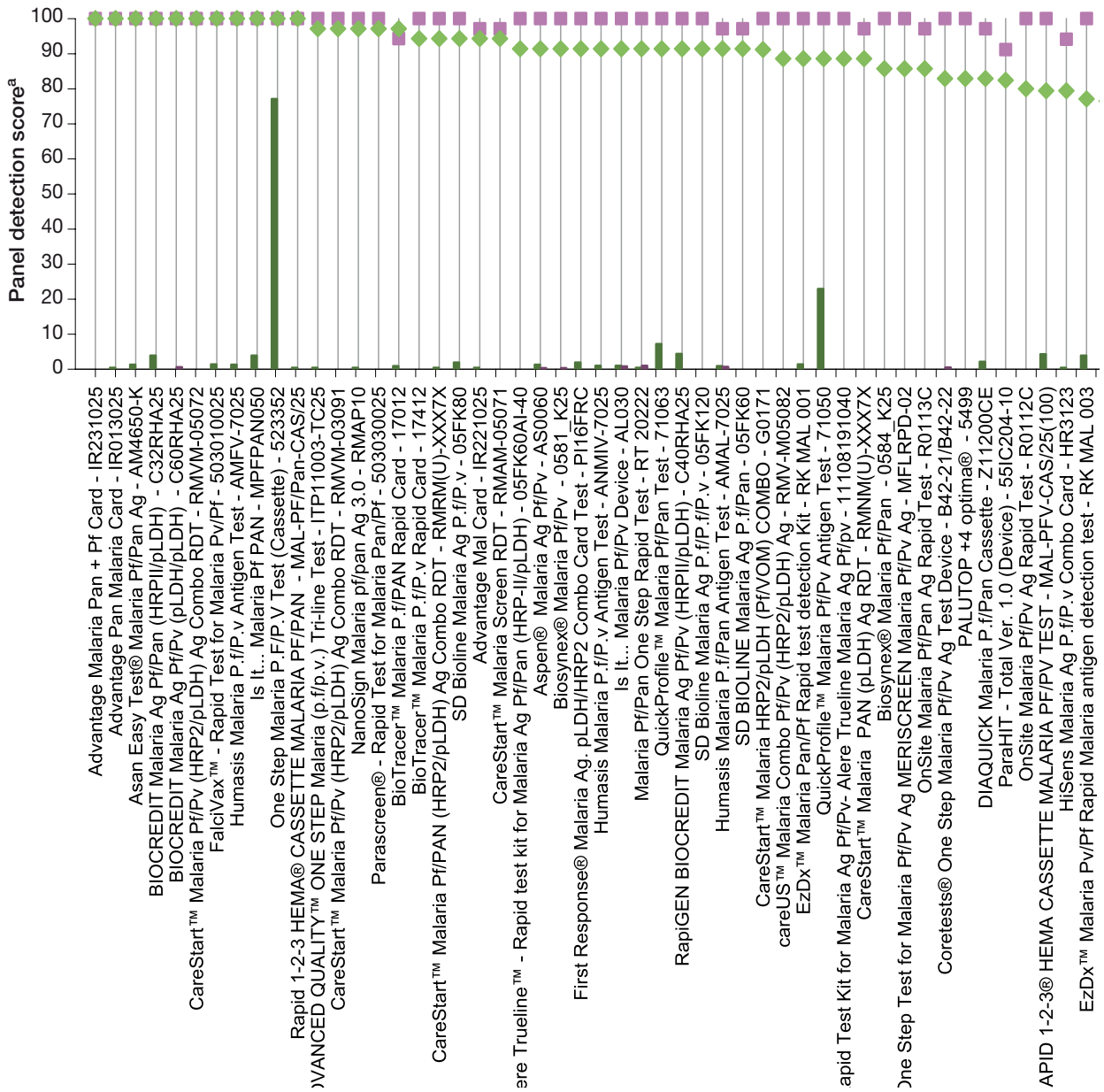
1.7. Product testing and WHO programme for prequalification of diagnostics and medical devices

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. As of 1 January 2018, WHO prequalification will become a requirement for WHO procurement. Therefore, manufacturers are strongly encouraged to apply.[1] Prequalified RDTs are listed in summary tables and at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/* (accessed 8 March 2017).

[1] *http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/*


Vikia® Malaria Ag Pf/Pan - 412499
Malaria Pf/PAN Test - PROMALPFV001
GMD Malaria Pf test - GMDMALPF001
DIAQUICK Malaria P.f. Cassette - W06200
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120
Rapid Test Kit for Malaria Ag Pf/Pv- Alere Trueline Malaria Ag Pf/pv - 11108191040
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
KHB® Malaria Ag (HRP2) Pf Rapid Test - R-409-50-C
ICT MALARIA DUAL TEST - ML03
First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
Biosynex® Malaria Pf/Pv - 0581_K25
Biosynex® Malaria Pf/Pan - 0584_K25
Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
GenBody™ Malaria Pf/Pan Ag - MALAG100
CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
Advantage Malaria Pan + Pf Card - IR231025
Maleriscan ® Malaria P.f Antigen Test - MAT-PF-50
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - PI16FRC
FalciVax™ - Rapid Test for Malaria Pv/Pf - 503010025
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test - RKMAL017
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood) - IMPF-C51
QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
QuickProfile™ Malaria Pf/Pan Test - 71063
Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
KHB® Malaria Ag P.f Rapid Test - KH-R-06-20
OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
EzDx™ Malaria Pan/Pf Rapid test detection Kit - RK MAL 001
Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
Parahit® f Ver 1.0 - Device - 55IC104-50
One Step Malaria P.f/Pan Whole Blood Test - W62-C
Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
Advantage Pan Malaria Card - IR013025
ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
OnSite Malaria Pf Ag Rapid Test - R0114C
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
Parahit f® Ver 1.0 - Dipstick - 55IC103-50
OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag - MPHRPD-01
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
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)j - 302040025
MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
ParaHITÂ®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-50
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Devicek - 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 pf (pLDH) / PAN-pLDH Test Device - MFV-124
Malaria Pf/Pv - GM002
Malaria Pf/ PAN - GM004
ABON™ Malaria P.f. Rapid Test Device (Whole Blood) - IMA-402
Advantage Mal Card - IR221025
200 parasites/µl
2000 parasites/µl
False-positive Plasmodium spp. rate (%)
Invalid rate (%)
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)

Figure S2: Malaria RDT performance in phase 2 of rounds 4–7 against wild-type (clinical) samples containing *P. vivax* at low (200) and high (2000) 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.

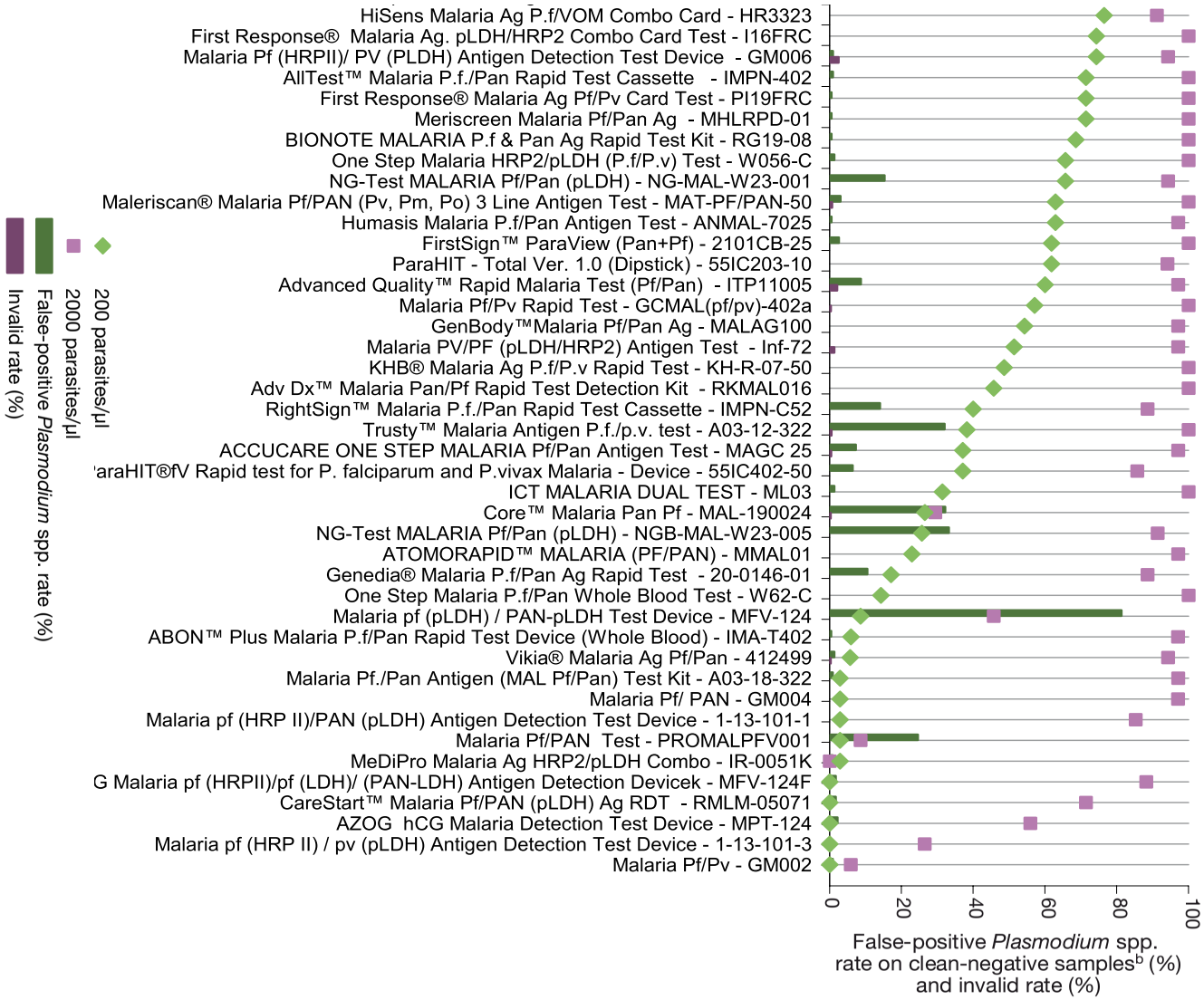
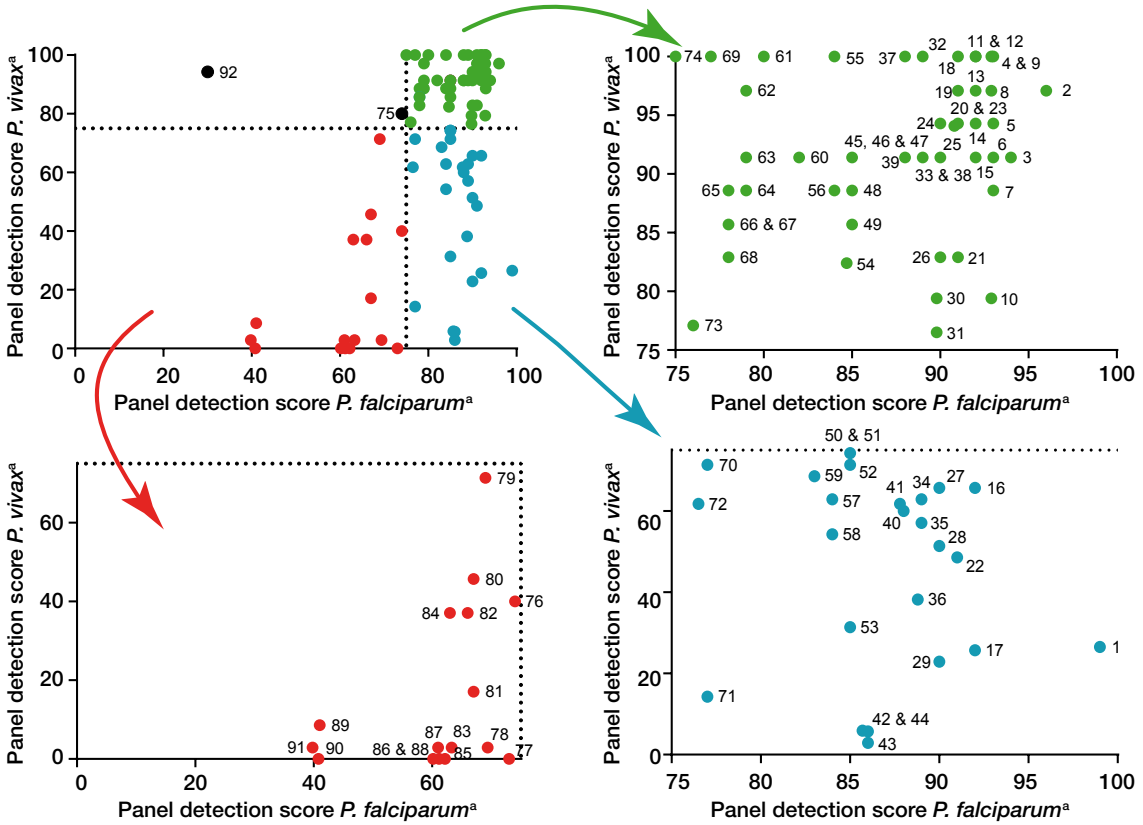

HiSens Malaria Ag P.f/VOM Combo Card - HR3323
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
FirstSign™ ParaView (Pan+Pf) - 2101CB-25
ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
GenBody™Malaria Pf/Pan Ag - MALAG100
Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
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
araHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-50
ICT MALARIA DUAL TEST - ML03
Core™ Malaria Pan Pf - MAL-190024
NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
ATOMORAPID™ MALARIA (PF/PAN) - MMAL01
Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
One Step Malaria P.f/Pan Whole Blood Test - W62-C
Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
Vikia® Malaria Ag Pf/Pan - 412499
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
Malaria Pf/ PAN - GM004
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
Malaria Pf/PAN Test - PROMALPFV001
MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
G Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Devicek - MFV-124F
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
AZOG hCG Malaria Detection Test Device - MPT-124
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
Malaria Pf/Pv - GM002
Invalid rate (%)
False-positive Plasmodium spp. rate (%)
2000 parasites/µl
200 parasites/µl
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and 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 4–7 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low parasite density (200 parasites/µL)



1 Core™ Malaria Pan Pf - MAL - 190024
2 BioTracer™ Malaria P.f/PAN Rapid Card - 17012
3 SD BIOLINE Malaria Ag P.f/Pan - 05FK60
4 Is It... Malaria Pf PAN - MPFPAN050
5 CareStart ™ Malaria Screen RDT - RMAM-05071
6 Aspen® Malaria Ag Pf/Pv - AS0060
7 careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
8 NanoSign Malaria pf/pan Ag 3.0 - RMAP10
9 Humasis Malaria P.f/P.v Antigen Test - AMFV-7025
10 RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST - MAL-PFV-CAS/25(100)
11 Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN - MAL-PF/Pan-CAS/25
12 One Step Malaria P.F/P.V Test (Cassette) - 523352
13 ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test - ITP11003-TC25
14 SD Bioline Malaria Ag P.f/P.v - 05FK80
15 RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
16 One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
17 NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
18 BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C32RHA25
19 CareStart ™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
20 BioTracer™ Malaria P.f/P.v Rapid Card - 17412
21 PALUTOP +4 optima® - 5499
22 KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
23 SD BIOLINE Malaria Ag Pf/ Pan - 05FK66
24 CareStart ™ Malaria Pf/PAN (HRP2/pLDH) Ag COMBO RDT - RMRM(U)-XXX7X
25 Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
26 DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
27 NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
28 Malaria PV/PF (pLDH/HRP2) Antigen Test- Inf-72
29 ATOMORAPID™ MALARIA (PF/PAN) - MMAL01
30 HiSens Malaria Ag P.f/P.v Combo Card - HR3123
31 HiSens Malaria Ag P.f/VOM Combo Card - HR3323
32 CareStart ™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT - RMVM-05072
33 Malaria Pf/Pan One Step Rapid Test - RT 20222
34 Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
35 Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
36 Trusty™ Malaria Antigen P.f./p.v. test - A03-12-322
37 Asan Easy Test® Malaria Pf/Pan Ag - AM4650-K
38 Is ItÖ Malaria Pf/Pv Device - AL030
39 Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
40 Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
41 FirstSign™ ParaView (Pan+Pf) - 2101CB-25
42 Vikia® Malaria Ag Pf/Pan - 412499
43 Malaria Pf/PAN Test - PROMALPFV001
44 ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
45 Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
46 Biosynex® Malaria Pf/Pv - 0581_K25
47 SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120
48 Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv - 11108191040
49 Biosynex® Malaria Pf/Pan - 0584_K25
50 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
51 Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
52 First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
53 ICT MALARIA DUAL TEST - ML03
54 ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
55 Advantage Malaria Pan + Pf Card - IR231025
56 CareStart ™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
57 Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
58 GenBody™ Malaria Pf/Pan Ag - MALAG100
59 BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
60 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - PI16FRC
61 FalciVax™ - Rapid Test for Malaria Pv/Pf - 503010025
62 Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
63 QuickProfile™ Malaria Pf/Pan Test - 71063
64 QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
65 EzDx™ Malaria Pan/Pf Rapid test detection Kit - RK MAL 001
66 OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
67 One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
68 Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
69 Advantage Pan Malaria Card - IR013025
70 Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
71 One Step Malaria P.f/Pan Whole Blood Test - W62-C
72 ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
73 EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
74 BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
75 OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
76 RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
77 CareStart ™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
78 MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
79 AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
80 Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
81 Genedia® Malaria P.f/Pan Ag Rapid Test- 20-0146-01
82 ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
83 Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
84 ParaHIT® fV Rapid test for *P. falciparum* and *P. vivax* Malaria - Device - 55IC402-50
85 AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - MFV-124F
86 AZOG hCG Malaria Detection Test Device - MPT-124
87 Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
88 Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
89 Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
90 Malaria Pf/Pv - GM002
91 Malaria Pf/ PAN - GM004
92 Advantage Mal Card - IR221025

[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 1–7

Manufacturer	Product name	Product code*	Product resubmission Round	
			Voluntary	Compulsory
Access Bio, Inc.	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-05072[a]	2, 4, 7	
	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	RMWM(U)-XXX7X[b]	2, 4	
	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM(U)-XXX7X[c]	1	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	RMRM(U)-XXX7X	1	5
	CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM(U)-XXX7X[e]	1	5
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X[f]	2	6
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071[g]	3	7
	CareStart™ Malaria Screen RDT	RMAM-05071[h]	3	7
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.[l]	ParaHIT® - f (Device)[j]	551C104-50	3	7
	ParaHIT® - f (Dipstick)[k]	551C103-50	3	7
ASAN Pharmaceutical Co., Ltd	Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	5, 7	
AZOG	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device[l]	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.	BioTracerTM Malaria P.f/PAN Rapid Card	17012	5, 6, 7	
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, 7	
	One Step Malaria P.f Test[m]	W37-C	2, 3, 4, 6, 7	
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	7
	ICT Malaria Dual Test	ML03	3, 5, 7	
InTec Products, Inc.	Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	1, 3, 7	5
	Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	3, 6, 7	
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
Lumiquick Diagnostics Inc.	QuickProfileTM Malaria Pf/Pv Antigen Test	71050	6, 7	
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for P. falciparum Malaria (Ver. 3)[n]	30301025	1, 3, 4	
	Paracheck® Pf Dipstick - Rapid test for P. falciparum Malaria (Ver.3)[n]	30302025	1, 3, 4	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[o]	I16FRC25	1, 2, 5	
	First Response Malaria Ag P. falciparum(HRP2) Card Test	I13FRC25	1	5
RapiGEN Inc.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	5, 6, 7	
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[p]	1, 3	
	Malaria Rapid Pf /Clearview ®Malaria Pf	VB01	1, 3, 5	
	Malaria Rapid Dual/Clearview® Malaria Dual Test Device	VB20[p]	1, 3, 5	
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	1, 3	
	Parabank™ Device - Rapid test for Malaria Pan	50301025	1, 3	
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025; 503030025 (rd 6)	1, 3, 4, 5, 6	
	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025; 503010025 (rd 6)	2, 4, 6	

* 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.

[a] Previously listed with product code G0161 for the Access Bio Inc product. Previously co-listed with G0161-ET, the equivalent Access Bio Ethiopia product. Access Bio Ethiopia products are now listed as separate products from separate manufacturers and not considered resubmissions.

[b] Previously listed with product code G0171 for the Access Bio Inc product. Previously co-listed with G0171-ET, the equivalent Access Bio Ethiopia product. Access Bio Ethiopia products are now listed as separate products from separate manufacturers and not considered resubmissions.

[c] Previously listed with product code G0141 for the Access Bio Inc product. Previously co-listed with G0141-ET, the equivalent Access Bio Ethiopia product. Access Bio Ethiopia products are now listed as separate products from separate manufacturers and not considered resubmissions.

[d] Previously listed with product code G0131/G0131-ET

[e] Previously listed with product code G0111

[f] Previously listed with product code G0181/G0181-ET

[g] Previously listed with product code G0121

[h] Previously listed with product code G0231

[l] Arkray Healthcare Pvt. Ltd. was formerly Span Diagnostics Ltd.

[j] New product codes have been in place since round 3, the previous code was 55IC102-10.

[k] New product codes have been in place since round 3, the previous code was 55IC101-10.

[l] 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.

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

[n] Ver.3 was introduced after round 1

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

[p] 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 4–7 against wild type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) and high (2000) 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 parasites/µl		Clean negative samples			
							Pf samples	Pv samples	Pf samples	Pv samples				
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
Pf only														
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	4	No
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	80.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test[j]	ITP11002-TC25	InTec Products, Inc.	93.0	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	7	Yes
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
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	98.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9 (231)	0.1	7	Yes
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	93.0	NA	100.0	NA	NA	0.7	NA	0.0	1.3	0.0	7	Yes
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	6	Yes
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	97.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
CareStart™ Malaria HRP2 (Pf)	RMOM(U)-XXX7X	Access Bio, Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	5	Yes[m]
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	96.0	NA	100.0	NA	NA	0.0	NA	0.0	0.4	0.0	7	Yes
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X	Access Bio, Inc.	91.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line[k]	RMSM-05071	Access Bio, Inc.	94.0 (94/38)	NA	99.0 (99/92)	NA	NA	2.1	NA	1.4	0.4	0.0	7	Yes
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	94.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	7	Yes
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	86.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	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 MALARIA P.F. CASSETTE TEST[j]	ML01	ICT INTERNATIONAL	94.0	NA	100.0	NA	NA	5.0	NA	1.4	1.7	0.0	7	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 (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co.,Ltd.	85.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
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
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	NA	100.0	NA	NA	0.0 (139)	NA	0.0	0.0	0.1	7	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
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	86.0	NA	99.0	NA	NA	2.9	NA	1.4	0.4 (231)	0.1	7	Yes
One Step Malaria HRP2 (P.f) Test[j]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	93.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	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
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	73.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	7	No
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	6	Yes
PALUTOP + pf®	5531	ALLDIAG SA	92.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver.3)	302030025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	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	0.0	NA	0.0	0.9	0.0	4	No
Parahit f® Ver 1.0 - Dipstick[j]	55IC103-50	ARKRAY Healthcare Pvt Ltd[n]	74.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	No
Parahit® f Ver 1.0 - Device[j]	55IC104-50	ARKRAY Healthcare Pvt Ltd[n]	77.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	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

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 parasites/µl		Clean negative samples			
							Pf samples	Pv samples	Pf samples	Pv samples				
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
SD Bioline Malaria Ag P.f (HRP2/pLDH)[k]	05FK90	Standard Diagnostics, Inc.	88.0 (87/52)	NA	100.0 (100/97)	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	90.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0 (231)	0.1	7	Yes
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
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	67.0	45.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	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
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	85.0	91.4	98.0	100.0	1.3	0.0	1.0	0.0	0.0	0.0	7	Yes
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	69.0	71.4	96.0	100.0	1.3	0.0	2.0	0.0	0.9	0.0	7	No
Asan Easy Test® Malaria Pf/Pan Ag [j]	AM4650-K	ASAN Pharmaceutical Co., Ltd	88.0	100.0	98.0	100.0	0.5 (399)	0.0	1.0	0.0	1.3	0.1	7	Yes
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	93.0	91.4	98.0	100.0	0.3 (399)	1.4 (138)	1.0	0.0	1.3 (231)	0.3	7	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
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[k]	MFV-124F	AZOG, INC.	62.2 (62/3.1)	0.0	98.0 (98/37.8)	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3	4	No
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) [j]	C32RHA25	RapiGEN Inc.	91.0	100.0	99.0	100.0	0.0	0.0	0.5	0.0	3.9	0.0	7	Yes
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	6	No
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	85.0	85.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
BioTracer™ Malaria P.f/PAN Rapid Card [j]	17012	Bio Focus Co., Ltd.	96.0	97.1	99.0	94.3	0.8	0.7	0.5	2.9	0.9	0.0	7	Yes
CareStart™ MALARIA Pf/PAN (pLDH) Ag RDT [j]	RMLM-05071	Access Bio, Inc.	73.0	0.0	100.0	71.4	0.0	0.7	0.0	0.0	1.7	0.0	7	No
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag COMBO RDT	RMRM(U)-XXX7X	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 Screen RDT [j]	RMAM-05071	Access Bio, Inc.	93.0	94.3	99.0	97.1	1.3	0.0	0.5	0.0	0.0 (231)	0.1	7	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
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	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	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 [j]	ML03	ICT INTERNATIONAL	85.0	31.4	98.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0	7	No
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	93.0	100.0	99.0	100.0	2.0	0.0	0.5	0.0	3.9	0.0	7	Yes
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 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 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/ 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

(continued)

Table S2: Malaria RDT phase 2 performance in rounds 4–7 against wild type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) and high (2000) 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 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]			
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
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
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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	92.0	25.7	98.0	91.4	0.8 (399)	3.6 (139)	1.0	4.3	33.2	0.2	7	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	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
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	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
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	92.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.4	0.0	7	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]
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 (p.f/p.v.) Tri-line Test[j]	ITP11003-TC25	InTec Products, Inc.	92.0	97.1	98.0	100.0	1.0	0.0	1.0	1.4 (69)	0.4	0.1	7	Yes
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	75.0	100.0	98.0	100.0	1.0 (399)	0.0 (139)	1.0 (199)	1.5 (68)	0.0 (230)	0.6	7	Yes
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	85.0	91.4	99.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0 (229)	0.3	7	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 Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	91.0	97.1	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT[j]	RMVM-05072	Access Bio, Inc.	89.0	100.0	99.0	100.0	1.8	0.0	2.0	0.0	0.0 (231)	0.1	7	Yes[m]
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	93.0	88.6	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
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	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 (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 Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	57.1	99.0	100.0	0.0	0.0	0.5 (199)	0.0	0.0 (231)	0.3	7	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

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 parasites/µl		Clean negative samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples: False positive non-Pf infection[e]	Pv samples: False positive Pf infection[f]	Pf samples: False positive non-Pf infection[g]	Pv samples: False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
One Step Malaria HRP2/pLDH (P.f/P.v) Test [j]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	92.0	65.7	100.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0	7	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 Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	78.0	85.7	100.0	100.0	0.5	0.7	0.0	1.4	0.0	0.0	7	Yes
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	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 Antigen Test [j]	71050	Lumiquick Diagnostics Inc.	79.0	88.6	99.0	100.0	39.8	0.0	27.5	0.0	22.9 (231)	0.1	7	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	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]
Rapid Test Kit for Malaria Ag Pf/Pv - Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	85.0	88.6	98.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
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
Pf, Pf and Pv														
SD Bioline Malaria Ag P.f/P.f/P.v [k]	05FK120	Standard Diagnostics, Inc.	85.0 (84/36)	91.4	100.0 (100/98)	100.0	0.0	0.0	0.5	0.0	0.0	0.0	6	Yes
Pf, Pv and Pan														
PALUTOP +4 optima®	5499	ALLDIAG SA	91.0	82.9[p]	99.0	100.0[p]	1.3	0.7	0.5	0.0	0.0	0.0	7	Yes
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	99.0	55.9	NA	NA	NA	NA	2.2	0.2	4	No
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM(U)-XXX7X	Access Bio, Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0	5	Yes[m]

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; Round 7, 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; Round76, 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; Round 7, 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; Round 7, 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; Round 7, 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; Round 7, 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; Round 7, n=220

[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). The results in brackets are the PDS based alone on HRP2 and Pf-pLDH test lines, respectively.

[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; Round 7, n=1210

[m] Indicates a WHO prequalified product

[n] ARKRAY Healthcare Pvt. Ltd. was formerly Span Diagnostics 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 4–7 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 room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			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	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage 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 tests															
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
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test [a]	ITP11002-TC25	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria HRP2 (Pf)	RMOM(U)-XXX7X	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line [b]	RMSM-05071	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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 MALARIA P.F. CASSETTE TEST [a]	ML01	ICT INTERNATIONAL	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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 (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
One Step Malaria HRP2 (P.f) Test [a]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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 Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
PALUTOP + pf®	5531	ALLDIAG SA	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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 1.0 - Dipstick [a]	55IC103-50	ARKRAY Healthcare Pvt Ltd c	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Parahit® f Ver 1.0 - Device [a]	55IC104-50	ARKRAY Healthcare Pvt Ltd c	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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) [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 P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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

Table S3 *(continued)*

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			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	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
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
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	7
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
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	46.7	70.0	33.3	100.0	100.0	100.0	7
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	16.7	90.0	100.0	100.0	7
Asan Easy Test® Malaria Pf/Pan Ag [a]	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	100.0	100.0	100.0	100.0	100.0	76.7	50.0	10.0	100.0	100.0	100.0	7
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	50.0	90.0	100.0	100.0	100.0	100.0	7
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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) [a]	C32RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	26.7	6.7	100.0	100.0	100.0	7
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
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	7
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	70.0	100.0	100.0	100.0	7
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT [a]	RMLM-05071	Access Bio, Inc.	100.0	96.7	93.3	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	7
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag COMBO RDT	RMRM(U)-XXX7X	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 Screen RDT [a]	RMAM-05071	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	7
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
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	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	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 [a]	ML03	ICT INTERNATIONAL	100.0	100.0	100.0	100.0	100.0	100.0	3.3	3.3	13.3	90.0	100.0	100.0	7
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	100.0	93.3	100.0	100.0	100.0	100.0	93.3	93.3	93.3	100.0	100.0	100.0	7
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 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 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/ 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
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
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

(continued)

Table S3: Malaria RDT rounds 4–7 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	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			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	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	100.0	100.0	100.0	100.0	100.0	100.0	53.3	86.7	66.7	100.0	100.0	100.0	7
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	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
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd. [d]	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. [d]	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	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
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-Pf/Pan-CAS/25	Hema Diagnostic Systems	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	33.3	100.0	100.0	100.0	7
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	20.0	100.0	100.0	60.0	100.0	5
SD BIOLINE Malaria Ag P.f/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
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	60.0	0.0	5
Pf and Pv/Pvom															
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test [a]	ITP11003-TC25	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	93.3	86.7	58.6	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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 Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT [a]	RMVM-05072	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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	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 (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 Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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
One Step Malaria HRP2/pLDH (P.f/P.v) 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	7
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 Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
OnSite Malaria Pf/Pv Ag Rapid Test	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. [d]	100.0	96.7	96.7	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	5
QuickProfile™ Malaria Pf/Pv Antigen Test [a]	71050	Lumiquick Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6

Table S3 *(continued)*

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			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	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Rapid Test Kit for Malaria Ag Pf/Pv - Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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															
PALUTOP +4 optima®	5499	ALLDIAG SA	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	7
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 PAN (pLDH) Ag RDT	RMNM(U)-XXX7X	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5

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 HRP2 or Pf-pLDH). Results based on stability of individual test lines is presented in the following table:

[c] Arkray Healthcare Pvt. Ltd. was formerly Span Diagnostics Ltd.

[d] Span Diagnostics Ltd. is now Arkray Healthcare Pvt. Ltd.

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (pan line)			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	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - (Pf(HRP2) line)	RMSM-05071	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - (Pf(pLDH) line)			100.0	50.0	50.0	100.0	50.0	50.0	NA	NA	NA	NA	NA	NA	7
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)			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)			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)			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 1–7 that have been removed from summary results listings

Manufacturer	Product name	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	536-25DB
Abon Biopharm (Hangzhou) Co. Ltd. (Iverness Medical)	ABON Malaria Pan/P.f.Rapid Test Device (whole blood)	IMA-B402
Access Bio, Inc.	CareStart™ Malaria/Pregnancy (HRP2/pLDH/ HCG)	RRHM(U)-XXX7X[a]
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
AZOG, Inc	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V
	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R
Bhat Bio-Tech India (P) Ltd	Maleriscan® Malaria Pf/Pv	MAT-50
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10
	NanoSign Malaria Pf/Pv Ag	RMAD10
BioNote,Inc.	BIONOTE MALARIA P.f&P.v Ag Rapid Test Kit	RG19-12
Biosynex	IMMUNOQUICK CONTACT falciparum	0519K25
	Immunoquick Malaria +4	0506_K25
	IMMUNOQUICK CONTACT Malaria +4	0525K25
Core Diagnostics	Core™ Malaria Pf	MAL-190020
	Core™ Malaria Pv/Pf	Mal-190022
	Core™ Malaria Pan/Pv/Pf	Mal-190026
CTK Biotech, Inc.	OnSite Pf Ag Rapid Test	R0114C
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024
Dima • Gesellschaft für Diagnostika mbH	Malaria Pan test	MAL-W23N-001
Diagnostics Automation/Cortez Diagnostics Inc.	Malaria P.F/Vivax	172110P-25
Guangzhou Wondfo Biotech Co. Ltd.	One Step Malaria P.f./Pan Whole Blood Test	W56-C
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
J. Mitra & Co. Pvt. Ltd.	Advantage Malaria Card	IR211025
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
Real World Diagnostics	Malaria Pf/PAN Test[X]	PROMALPFV001
Span Diagnostics	ParaHIT®-f Dipstick	551C010-50/25977
	ParaHIT®- f Device	551C102-50/25975
	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
	diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3
	diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4
	diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40
	SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100
	SD BIOLINE Malaria Ag Pf/ Pan	05Fk66
	SD BIOLINE Malaria Ag Pv	05FK70
	SD BIOLINE Malaria Ag P.f/Pan	05FK63[b]
	SD BIOLINE Malaria Ag P.f/P.v	05FK83[c]
	SD BIOLINE Malaria Ag Pf	05FK53[d]
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 listed with product code G0221

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

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

[d] 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 2015, there were an estimated 212 million cases (with an uncertainty range of 148 million to 304 million) and an estimated 429 000 deaths (with an uncertainty range of 235 000 to 639 000). Approximately 90% of these deaths occurred in sub-Saharan Africa, and just over 70% were of children under 5 years. Malaria remains endemic in 91 countries and territories, and, while parasite-based diagnosis is increasing, national surveys between 2013 and 2015 suggest approximately 31% of suspected malaria cases in sub-Saharan Africa were not confirmed with a diagnostic test, 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. Since 2009, these data have guided procurement decisions by WHO, other United Nations agencies and national governments and have formed the laboratory evaluation component of the WHO prequalification process for malaria RDTs. Meeting WHO prequalification criteria has not previously been a requirement for WHO procurement; however, as of 1 January 2018, only those products that meet WHO prequalification requirements will be eligible for WHO procurement.[1] This report provides the results of round 7 of product testing, performed at the CDC during 2015–2016, with data on the performance of 46 products. This round adds to the evaluations of rounds 1–6 (*3*–*8*), 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.

[1] http://www.who.int/malaria/news/2016/rdt-procurement-criteria/en/ (accessed 8 March 2017)

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 46 products from 26 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. In round 7 a new assessment of compliance with good practices for product labelling and instructions for use was included. 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 15 products that had been tested in previous rounds comprised five compulsory resubmissions and 10 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 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).

WHO product testing constitutes the laboratory evaluation component of the WHO prequalification process for malaria RDTs (*10*), which also includes a standardized dossier review and a manufacturing site inspection to ensure safety, quality and performance comprehensively. WHO prequalification of in vitro diagnostics, established in 2008, is used by all United Nations agencies to determine the eligibility of tests for HIV, hepatitis B and C and syphilis for procurement and by national authorities as a complement to their regulatory approvals. WHO prequalification will determine the eligibility of malaria RDTs for procurement as of 1 January 2018. The results of WHO product testing will continue to be used as the independent laboratory evaluation component of the prequalification process.

Compulsory resubmission was introduced in round 5. Products that are due for resubmission (every 5 years) that are not submitted are removed from the summary results (Tables S2 and S3) and the online interactive database and appear only in the full round-specific product testing report. These products will not be eligible for WHO procurement. A product is also de-listed 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 identify clinical malaria reliably in many settings (*11*), and a higher parasite density (2000 parasites/µL).

For the purposes of this report, the main measure of performance is the panel detection score (PDS), the percentage of malaria samples in 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 7. 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, 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 7, the results for five products submitted for compulsory retesting showed an average PDS decrease of 3.5 percentage points as compared to the previous evaluation round, for detection of *P. falciparum* (range, –16 to +7; 2/5 had a better PDS). Only two of these tests also targeted *P. vivax* at 200 parasites/µL; the mean change in PDS was – 42.9 percentage points (range, –91 to +5). The mean change in the false-positive rate of clean negatives was – 0.4 percentage points (range, –2.5 to + 1.7%). Two of the five tests had improved false-positive rates (one showed no change, and two showed increases). Overall, most of the differences were decreases in PDS and improvements in false-positivity rates in comparison with previous testing. Among the voluntary resubmissions, 80% (8/10) and 75% (6/8) of products showed the same or better detection of *P. falciparum* and *P. vivax* at 200 parasites/µL, respectively. Specifically, in tests for *P. falciparum*, the mean change in PDS was +9.2 percentage points (range, –8 to +40; n = 10); 8/10 had improved PDS. For *P. vivax*, the mean change in PDS was +30.7 percentage points (range, –8.6 to +65.7; n = 8), and 6/8 had a better PDS. The mean change in the false-positive rate on clean negatives was 1.9 percentage points (range, –7.3 to + 22.9%; n = 10), while 2/10 had a better false-positive rate.

In combination tests, no significant correlation was found between the changes in *P. falciparum* and *P. vivax* detection ($p = 0.7$), suggesting that the changes in the detection of the two parasite species were independent.

In round 7, none of the products had very high false-positive rates when tested against clean negatives, as in round 6. These are an improvement from the high rates observed in rounds 4 and 5. In contrast, more products reacted against blood samples containing specific immunological abnormalities (and against samples containing non-*Plasmodium* infectious agents), and these false-positive rates were higher than those 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 variation among lots in round 7 (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 *P. falciparum* HRP2 test lines in the majority of products showed good heat (thermal) stability 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 after 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. As in round 6, products were assessed for heat stability against a wild-type *P. vivax* sample. While most of the products performed well, with high positivity rates after 2 months' storage at 45°C and 75% humidity, others showed some drop in performance after storage, with little difference between pan-pLDH and *P. vivax* pLDH in test line stability.

The frequencies of anomalies that can interfere with test interpretation were recorded. In round 7, 33 of the 46 products had one to five different types of anomaly (Annex S2, Table 8, Fig. 30). Incomplete clearing and red background (not obscuring the test lines) were the most common anomalies, seen in 48% and 24% of products, respectively. Incomplete

migration, failed migration and a red background obscuring the test lines were the next most common anomalies, in 15%, 11% and 11% of products, respectively. Most of the products with anomalies (31/33) had anomalies in < 1% of the tests, while two products had anomalies in 1.4% of tests (Table 8). This rate is far lower than in round 6, in which all products had one to six anomalies, and approximately half had a frequency > 2%.

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.

In round 7, for the first time, adherence to a list of recommendations on instructions for use and product labelling was assessed (Fig. 31-38). Products generally scored well in this assessment for labelling of the main device and labelling of the device packaging and of the primary product box, with some exceptions, especially in warnings and precautions. The scores for adherence to recommendations on labelling of buffer bottles and other accessories were lower. The instructions for use were highly variable, with some important omissions, particularly on laboratory safety, product performance and interpretation.

2.4. Use of the results

Box 3 lists WHO's current minimum criteria for selecting RDTs. With the upcoming transition to WHO prequalification as a requirement for malaria RDT procurement, the findings from dossiers and site inspections will also be considered; however, the performance requirements will remain the same. The results in Tables S2, S3 and 5 are colour-coded to reflect achievement of these requirements, as well as current 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 (*15*). 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.

The results of product testing are reported by product, with the product name and code. The same RDT may be sold in a variety of configurations, such as single or multi-kits, different numbers of tests per box, with or without certain accessories; and they are assigned a distinct product code on this basis. The reports gives the precise name and product code provided by the manufacturer for testing. Procurers should contact the manufacturer for a list of product configurations prior to purchase.

Annex S3 outlines 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, such as 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 *Recommended selection criteria for procurement of malaria rapid diagnostic tests (16)*, published as a WHO information note in 2016,[1] and guidance on implementation in *Universal access to malaria diagnosis* (*17*).

[1] http://www.who.int/malaria/publications/atoz/rdt-selection-criteria.pdf

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 (*11*); however, in many 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 are 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 most relevant to human health (*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 (*17–25*). 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 (*11*).

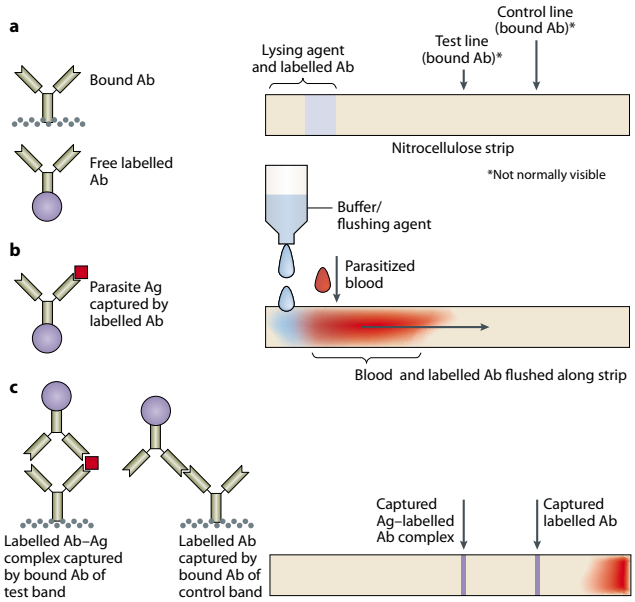
The number of RDTs available on the market grew rapidly after their introduction in the late 1990s; sales reported by 41 manufacturers showed a peak of 320 million tests sold in 2013. Since 2013, there has been a global decline, due to decreasing sales in Asia, although sales in Africa have risen every year since 2008 (*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 (*26, 27*). 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 six rounds of product testing have been released annually since 2009 (*3–8*). This seventh report adds data on the performance of 29 new products and updated data on 17 resubmitted RDTs. Testing for round 7 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 19 of 100 *P. falciparum*, 5 of 35 *P. vivax* and 17 of 100 negative samples replaced (new) in round 7.

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



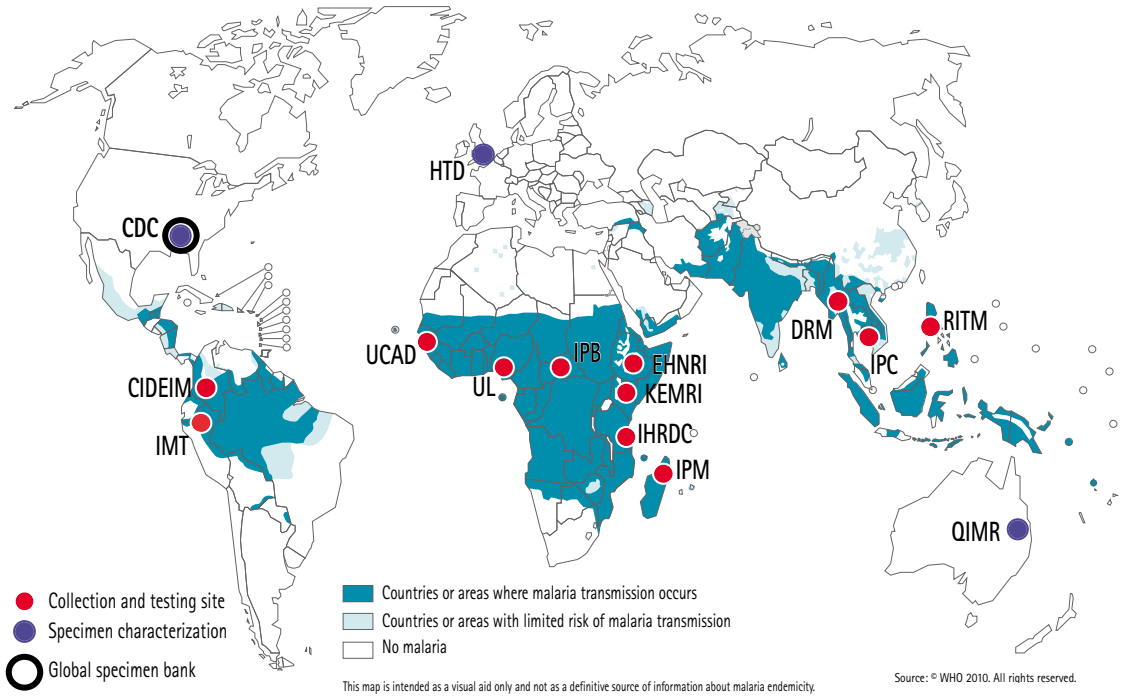
Mode of action of common malaria RDT format:

(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 July 2015, 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 7 and the conditions for participation in the evaluation programme (*29*). Manufacturers of products that had not been retested since round 3 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

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

Table 1a: Manufacturers and products accepted into round 7 of WHO malaria RDT product testing programme

Manufacturer	Product name	Product code[a]	Target antigen(s)
Access Bio, Inc.	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT[c]	RMVM-05072	V(pLDH), HRP2
	CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	F(pLDH), HRP2
	CareStart™ Malaria Screen RDT[b]	RMAM-05071	pan(pLDH), HRP2/F(pLDH)
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT[b]	RMLM-05071	pan(PLDH), F(pLDH)
Access Bio Ethiopia	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	HRP2
	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	V(pLDH), HRP2
Advy Chemical Private Limited	Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	pan(pLDH), HRP2
	Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	HRP2
Alere Medical Private Limited	Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	pan(pLDH), HRP2
	Rapid Test Kit for Malaria Ag Pf/Pv- Alere Trueline Malaria Ag Pf/Pv	11108191040	V(pLDH), HRP2
ALLDIAG SA	PALUTOP +4 optima®	5499	pan(pLDH), V(pLDH), HRP2
	PALUTOP + pf®	5531	HRP2
ARKRAY Healthcare Pvt Ltd	Parahit® f Ver 1.0 - Device[b]	55IC104-50	HRP2
	Parahit f® Ver 1.0 - Dipstick[b]	55IC103-50	HRP2
ASAN Pharmaceutical Co., Ltd	Asan Easy Test® Malaria Pf/Pan Ag[c]	AM4650-K	pan(pLDH), HRP2
Aspen Laboratories Pvt. Ltd.	Aspen® Malaria Ag Pf/Pv	AS0060	V(pLDH), HRP2
	Aspen® Malaria Ag Pf	AS0015	HRP2
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f Rapid Card	17912	HRP2
	BioTracer™ Malaria P.f/PAN Rapid Cardc	17012	pan(pLDH), HRP2
Biosynex	Biosynex® Malaria Pf/Pv	0581_K25	V(pLDH), HRP2
	Biosynex® Malaria Pf/Pan	0584_K25	pan(pLDH), HRP2
DIALAB	DIAQUICK Malaria P.f. Cassette	W06200	HRP2
Guangzhou Wondfo Biotech Co., Ltd.	One Step Malaria HRP2 (P.f) Test[c]	W37-C	HRP2
	One Step Malaria HRP2/pLDH (P.f/P.v) Test[c]	W056-C	V(pLDH), HRP2
Hangzhou AllTest Biotech Co. Ltd.	AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Aldolase, HRP2
Hema Diagnostic Systems	Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	HRP2, pan(pLDH)
ICT INTERNATIONAL	ICT MALARIA DUAL TEST[c]	ML03	HRP2, pan(pLDH)
	ICT MALARIA P.F. CASSETTE TEST[b]	ML01	HRP2
InTec Products, Inc.	ADVANCED QUALITY ™ ONE STEP Malaria (p.f) Test[c]	ITP11002-TC25	HRP2
	ADVANCED QUALITY ™ ONE STEP Malaria (p.f/p.v.) Tri-line Test[c]	ITP11003-TC25	V(pLDH), HRP2
Lumiquick Diagnostics Inc.	QuickProfile™ Malaria Pf/Pv Antigen Test[c]	71050	V(pLDH), HRP2
Medical Diagnostech (Pty) Ltd	GMD Malaria Pf test	GMDMALPF001	HRP2
Real World Diagnostics	Malaria Pf/PAN Test	PROMALPFV001	HRP2, V(pLDH)
Medsource Ozone Biomedicals Pvt. Ltd.	Is It... Malaria Pf PAN	MPFPAN050	pan(pLDH), HRP2
Meril Diagnostics Pvt. Ltd.	One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	V(pLDH), HRP2
	One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	HRP2

Table 1a: *(continued)*

Manufacturer	Product name	Product code[a]	Target antigen(s)
NG Biotech	NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	HRP2, pan(pLDH)
RapiGEN Inc.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)[c]	C32RHA25	pan(pLDH), HRP2
	BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	V(pLDH), F(pLDH)
Shanghai Kehua Bio-engineering Co., Ltd.	KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	HRP2
Standard Diagnostics, Inc.[d]	SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	HRP2/F(pLDH)
	Alere™ Malaria Ag P.f	05FK140-40-0	HRP2
WELLS BIO, INC	careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	HRP2
	careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	V(pLDH), HRP2
Zhejiang Orient Gene Biotech Co., Ltd.	Malaria Pf Rapid Test	GCMAL(pf)-402a	HRP2
	Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	HRP2, V(pLDH)

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 previously submitted products which were submitted for compulsory restesting in round 7.

[c] Indicates products which have previously been submitted and were voluntarily resubmitted in round 7.

[d] An Alere company

Table 1b: Products due for compulsory resubmission in round 7

Manufacturer	Product name	Product Code	Participation in round 7[a]
ABON Biopharm (Hangzhou) Co. Ltd	ABON Malaria Pan/P.f. Rapid Test Device (Whole Blood)	IMA-B402	No
Access Bio, Inc.	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071[b]	Yes
	CareStart™ Malaria/Pregnancy (HRP2/pLDH/ HCG)	RRHM(U)-XXX7X[c]	No
	CareStart™ Malaria Screen RDT	RMAM-05071[d]	Yes
ACON Biotech (Hangzhou) Co. Ltd	Surestep™ Malaria Pf/Pan Rapid Test Device (Whole Blood)	IMA-T402	No
AZOG, Inc	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V	No
	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R	No
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10	No
	NanoSign Malaria Pf/Pv Ag	RMAD10	No
BioNote,Inc.	BIONOTE MALARIA P.f/P.v Ag Rapid Test Kit	RG19-12	No
Biosynex	IMMUNOQUICK CONTACT falciparum	0519K25	No
	IMMUNOQUICK CONTACT MALARIA +4	0525K25	No
Core Diagnostics	Core™ Malaria Pf	MAL-190020	No
	Core™ Malaria Pv/Pf	Mal-190022	No
	Core™ Malaria Pan/Pv/Pf	Mal-190026	No
CTK Biotech, Inc.	OnSite Pf Ag Rapid Test	R0114C	No
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024	No
Dima • Gesellschaft für Diagnostika mbH	Malaria Pan test	MAL-W23N-001	No
ICT International	ICT Diagnostics Malaria P.f	ML01	Yes
J. Mitra & Co. Pvt. Ltd.	Advantage Malaria Card	IR211025	No
Orgenics Ltd.	Clearview® Malaria pLDH	70884025	No
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40	No
Span Diagnotics Ltd.[e]	ParaHIT® - f (Device)	55IC102-10	Yes
	ParaHIT® - f (Dipstick)	55IC101-10	Yes
SSA Diagnostics & Biotech Systems	diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3	No
	diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4	No
	diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5	No
Vision Biotech (Pty) Ltd.	Clearview® Malaria Combo	VB11	No
	Clearview® Malaria Pf	VB01	No
Guangzhou Wondfo Biotech Co. Ltd.	One Step Malaria P.f./Pan Whole Blood Test	W56-C	No

[a] The results of the first testing of the products in this list that were not retested in round 7 have been removed from tables S2 and S3 and figs S1 and S2 and are listed in table S4.

[b] Previously listed with product code G0121

[c] Previously listed with product code G0221

[d] Previously listed with product code G0231

[e] Currently listed with product codes 55IC104-50 and 55IC103-50. Span Diagnostics is now ARKRAY Healthcare Pvt.Ltd.

the product definition[1], deadlines for document submission and payment of fees.

Twenty-seven manufacturers, proposing 45 products, responded to the call, and the products went forward for testing. A further product from one manufacturer was exceptionally accepted as a late entry, directly into phase 2, because of the urgent need for pf-pLDH-based RDTs in areas with a high prevalence of HRP2 deletions. Overall, 46 products from 27 manufacturers were tested in round 7 (Table 1a). Catalogue numbers and verification with manufacturers showed that 15 of the 46 products (33%) had been submitted previously to one or more rounds, including five (11%) scheduled for compulsory resubmission (Table 1b). All 45 products met the minimum performance requirements[2] in the initial evaluation against the *P. falciparum* culture-derived panel (phase 1) and were therefore evaluated fully in phase 2, with the additional product.

Of the 46 products that were fully evaluated, 19 are designed to detect *P. falciparum* alone, 13 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria, 13 to differentiate *P. falciparum* from *P. vivax* and one to detect and differentiate *P. falciparum*, *P. vivax* and other *Plasmodium* species. Of these products, five detected *P. falciparum* pLDH. Three products had separate Pf-pLDH detecting lines and two combined *P. falciparum* pLDH with HRP2 on the same line. Annexes 1 and 2 give a comprehensive overview of the product characteristics.

[1] 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=1, accessed 8 March 2017*).

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

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 (*28*). 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. A description of the ease of use of the products was completed on a standard form, and common anomalies were recorded. Evaluation of adherence to recommendations on instructions for use and labelling was introduced in round 7. Products were assessed against a list of preferred and required recommendations on the scope, format and terms used in the instructions for use and on the labelling of the box, the test device, its primary packaging, buffer bottle, other accessories.

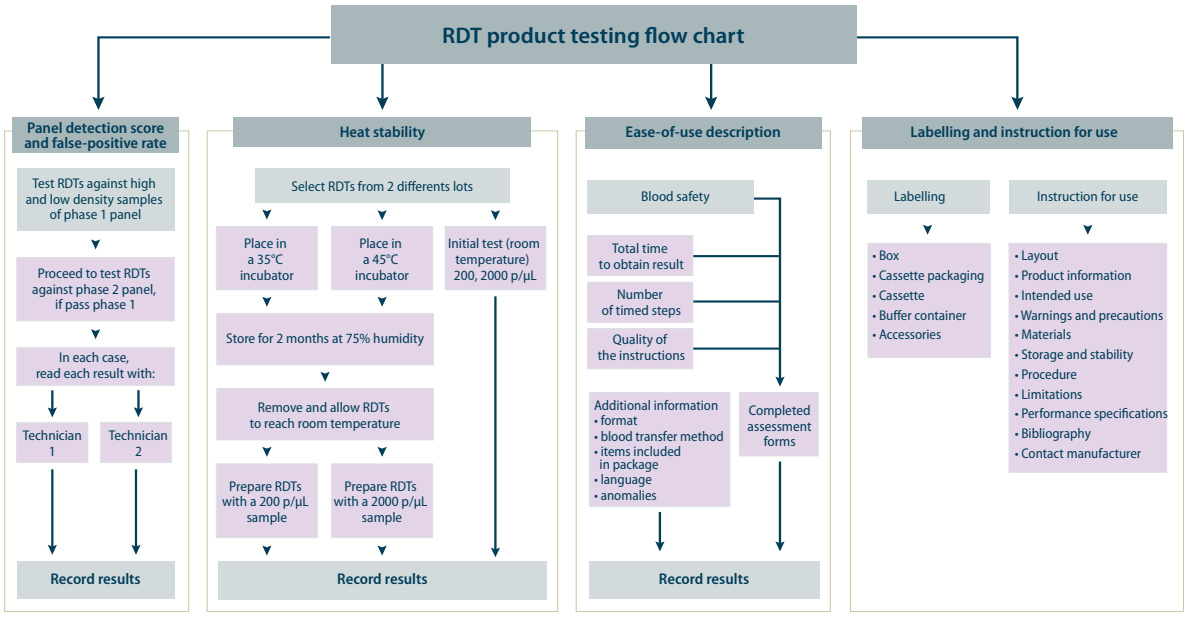
The testing and all the results were monitored by the WHO–FIND steering committee, and manufacturers were given 30 days to comment on the results for individual products before publication.

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

Figure 3: Overview of malaria RDT product testing



parasite density (2000[1] 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 (*27, 28*). Characterization results for each round are available in the reports of previous rounds (*3-8*). 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.

Some of the *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 (*30*). 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 (*30*). All specimens were derived from the CDC culture bank and diluted in O-positive blood from donors in the USA (*28*).

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 (*27*). 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 (Cambodia, Kenya, Madagascar, the Philippines and Senegal) that had been confirmed 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 nested-PCR.

[1] Three (3%) of the 100 high-parasite-density *P. falciparum* dilution samples contained 5000 rather than 2000 parasites/µL.

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

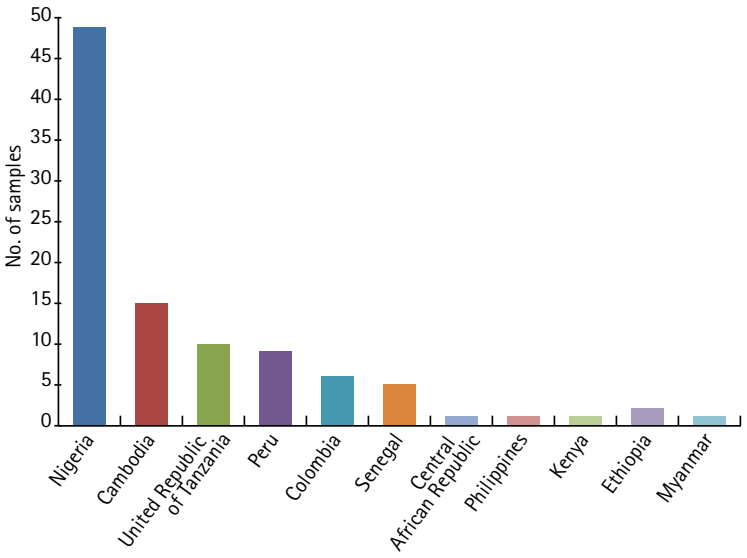


Figure 4b: Origin of phase 2 *P. vivax* wild-type (clinical) samples (n=35)

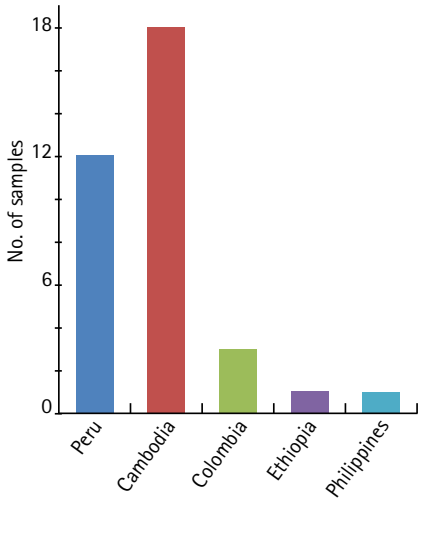


Table 2: Characteristics of *Plasmodium* spp. negative samples

Nature of negative sample[a]	No.
Clean-negative[b]	52
Anti-nuclear antibody positive (sera)	12
Anti-mouse antibody positive (plasma)	3
Rheumatoid factor positive (whole blood and sera)	6
Rapid plasma reagin positive (sera)	6
Chagas' disease antibody positive (plasma)	2
Dengue antibody positive (whole blood sera)	7
Leishmaniasis antibody positive (sera)	4
Schistosomiasis antibody positive (whole blood and sera)	8

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

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

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 and <50% false positive rate against clean negative samples.

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. 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 parasites/µL[2]) and 100 parasite-negative samples.
- Evaluation of heat stability for *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] at 200 parasites/µL, five RDTs from each lot against *P. falciparum* Nigeria XII strain at 2000 parasites/µL and four RDTs from each lot against a negative sample, 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

[1] A sample set usually consists of 13 *P. falciparum* specimens and 5 *P. vivax* specimens at 200 parasites/µL and 2000 parasites/µL and 13 malaria-negative samples.

[2] Three (3%) of the 100 *P. falciparum* high parasite density dilution samples contained 5000 parasites/µL rather than 2000.

[3] The *P. falciparum* sample had 18.8 ng/mL of HRP2, 21.1 ng/mL of pLDH and 0.49 ng/mL of aldolase.

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

Table 3: Malaria antigen concentrations (ng/mL) in round 7 wild-type, low parasite density (200 parasites/µL) samples

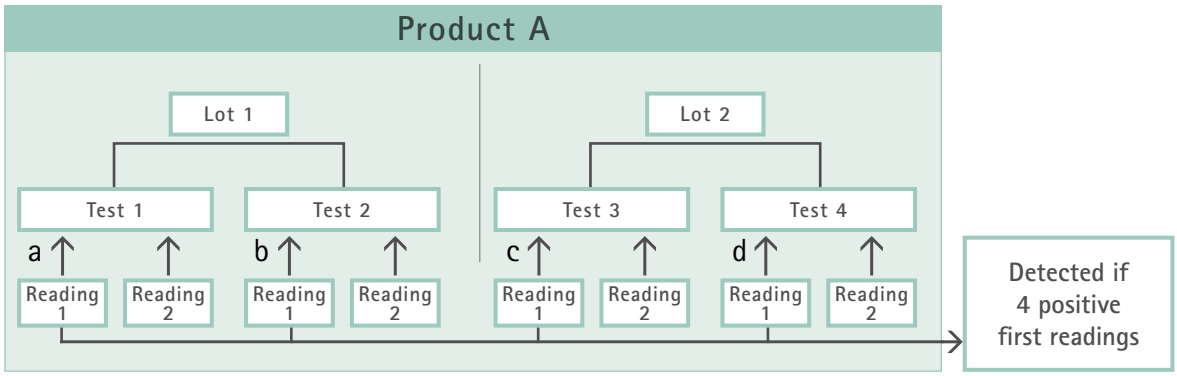
	pLDH		HRP2	Aldolase	
	P. falciparum	*P. vivax*	*P. falciparum*	*P. falciparum*	*P. vivax*
Mean	15.9	16.9	11.8	1.4	8.2
Median	13.0	16.6	6.8	1.3	8.0
Maximum	53.5	44.8	62.5	9.1	15.1
Minimum	0.2	1.6	0.7	0.0	3.2
Standard deviation	11.6	11.2	13.0	1.3	3.6

maintained for 60 days at room temperature (21-24°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 (*28*).
- Assessment of labelling, packaging and instructions for use: Technicians assessed the product components to determine whether they met each of the recommended or preferred criteria, assessed in the following categories:
  - labelling of the RDT box (58 criteria assessed);
  - labelling of the primary cassette packaging (16 criteria assessed);
  - labelling of the cassette (11 criteria assessed);
  - labelling of the buffer bottle (15 criteria assessed);
  - labelling of the accessories (transfer devices, lancets, alcohol swabs and desiccant) (19 criteria assessed); and
  - content and format of the instructions for use (119 criteria assessed). See supplemental files for full details.

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.

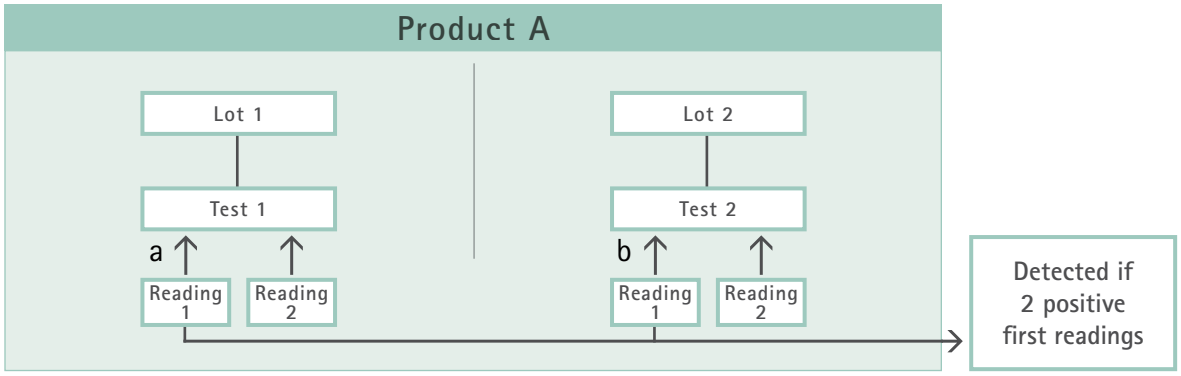


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[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

- RDT anomalies: During testing, technicians regularly reported the RDT anomalies listed below (not all of which were observed in round 7) 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)
  - 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.

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

5.9. Recording anomalies

Anomalies are defined as unexpected features that appear during performance of an RDT. Anomalies have been observed since round 1. After the appearance of each, technicians agreed on terms with which to identify them. During earlier rounds of testing, their presence was recorded informally (and reported to manufacturers), but, since round 6, the frequency of anomalies has been 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 and to 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), 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 in December 2016 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 7 (*28*). 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, using standard colour charts 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. Reading of the RDT results by the first and second technician is blinded.

7.3. Quality of WHO specimen bank samples

Standard operating procedures were established for the preparation of all specimen bank samples (*26*). Culture lines of parasites and wild-type samples were selected on the basis of previous evidence and data from specific studies. All diluted parasite sample aliquots 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 RDT 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 Fig. 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 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 been obtained, when read 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

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

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 parasites/µL. High inter-lot agreement indicates consistency in detecting malaria parasites. When one test is invalid and the other positive, positive agreement is recorded. Fig. 8 shows sample calculations for lot agreement.

9.5. Invalid tests

Invalid tests are those deemed invalid during testing of both lots, with samples at 200 parasites/µL and 2000 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)[2] 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. At some point during the 60-day incubation period for the late entry test (CareStart™ Malaria Pf/PAN (pLDH)- RMLM-05071), the humidity regulator in the 45°C stability chamber was compromised leading to water-soaking of all test boxes. The precise timing of this event and the effect on temperature and humidity are unknown. Testing was still performed because all cassette packaging was intact.

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-7 products. Photographs and descriptions are shown in Fig. AS2.1.

9.8. Labelling and instructions for use

For each product, technicians recorded whether the product met each of the recommended criteria. The results were pooled for analysis. The proportions of products that met a selection of recommended criteria is presented graphically in Figs 31–38.

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

[2] Fifteen tests per lot against 200 parasites/µL samples, five tests per lot against 2000 parasites/µL for *P. falciparum* samples, 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 the 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. ASSOCIATION 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 1–7 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. EVALUATION OF MALARIA RAPID DIAGNOSTIC TESTS IN THE LABORATORY AND IN THE FIELD

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 (*31*). 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 (*12–13*). 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 (*32*), which should be followed to improve the reproducibility and quality of the results.

12. RESULTS

12.1. Summary

Round 7 of WHO malaria RDT product testing provided results for 46 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 February 2016 and August 2016, approximately 65 000 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, i.e. *P. malariae, P. ovale*, could 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); WHO prequalification status is also indicated. When choosing an appropriate product, it is important also to review its thermal stability (Tables 6a and 6b) according to 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 1–6 (*3–8*), the false-positivity rates and *P. vivax* PDS and *P. vivax* positivity rates were similar to those in round 6, and better than in previous rounds.

  The median PDS for *P. falciparum* at low parasite densities in round 7 (89.5%) was slightly higher than in rounds 5 and 6 (both 86%) and similar to that seen in round 4 (89.3%). No products in round 7 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, 6 and 7 being 75.0%, 51.4%, 61.8%, 65.7%, 82.9% and 90.0%, respectively. Six 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 a median overall false-positive rate of 2.8%.
- 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. This increases the number of well-performing tests from that in rounds 1–6.
- The one *P. falciparum*-only test detecting pf-pLDH did not meet procurement criteria; however, one combination non-HRP2 detecting RDT met criteria for *P. falciparum* and *P. vivax* targeting pf-pLDH and pan-pLDH, respectively.
- 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 parasites/µL.
- All, except two, round-7 products had an HRP2 detecting line, and most of these products achieved a high PDS for *P. falciparum* detection at low parasite density.
- Several combination tests achieved PDS at the upper end of the range for both *P. falciparum* and *P. vivax*. (Fig. S3).
- There was minimal lot-to-lot variation in the test performance of round-7 products.
- Overall, approximately half of the combination tests with Pf and Pan lines in which HRP2 was used for detection of *P. falciparum*, returned positive results only on the HRP2 band at lower densities of *P. falciparum*. Results were product-specific, with values ranging from 5% to 89%. Manufacturers' instructions should therefore classify *P. falciparum* infections as positive in either the HRP2 test line alone or in combination with the pan-pLDH line.

Table 4: Summary of phase 1 performance of 45 malaria RDTs[a] against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite density (parasites/µl)

Product	Product code	Manufacturer	Panel detection score[b] (n=20)		False-positive non-Pf infection[c] (%)		Invalid rate (%) (n=120)
			200 parasites/µl	2000 parasites/µl	200 parasites/µl (n=80)	2000 parasites/µl (n=40)	
Pf only							
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	100.0	100.0	NA	NA	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	100.0	100.0	NA	NA	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.[e]	100.0	100.0	NA	NA	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	100.0	100.0	NA	NA	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	100.0	100.0	NA	NA	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	100.0	100.0	NA	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	100.0 (100/35)[d]	100.0 (100/95)[d]	NA	NA	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	100.0	100.0	NA	NA	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	100.0	100.0	NA	NA	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	100.0	100.0	NA	NA	0.0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	NA	NA	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	NA	NA	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	100.0	100.0	NA	NA	0.5
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	NA	NA	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	95.0	100.0	NA	NA	0.0
PALUTOP + pf®	5531	ALLDIAG SA	100.0	100.0	NA	NA	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	80.0	100.0	NA	NA	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	100.0	100.0	NA	NA	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.[e]	90.0	100.0	NA	NA	0.0
Pf and Pan							
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	75.0	100.0	0.0	0.0 (39)	0.5
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	100.0	100.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	80.0	100.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	100.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	80.0	100.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	100.0	100.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	100.0	100.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	100.0	100.0	0.0	0.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	100.0	100.0	0.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	100.0	100.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	100.0	95.0	0.0	2.5	0.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	100.0	100.0	0.0	0.0	0.0
Pf and Pv							
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	100.0	100.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	80.0	100.0	0.0 (78)	0.0	1.5
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	100.0	100.0	0.0	0.0	0.5
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	100.0	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[b] (n=20)		False-positive non-Pf infection[c] (%)		Invalid rate (%) (n=120)
			200 parasites/µl	2000 parasites/µl	200 parasites/µl (n=80)	2000 parasites/µl (n=40)	
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	100.0	100.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	100.0	100.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	0.0	0.0	0.0
Malaria Pf/PAN Test	PROPMALPFPV001	Real World Diagnostics	100.0	100.0	25.0	97.5	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	90.0	100.0	0.0 (79)	0.0	0.5
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	100.0	100.0	12.5	15.0	0.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	100.0	100.0	0.0	0.0	0.0
Pf, Pv and Pan							
PALUTOP +4 optima®	5499	ALLDIAG SA	100.0	100.0	1.3	0.0	0.0

NA, not applicable

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

[a] Phase-1 performance tests for CareStart Pf/PAN (pLDH) Ag RDT (RMLM-05071) not conducted

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

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

[e] An Alere company

Table 5: Summary of phase 2 performance of 46 malaria RDTs against wild-type (clinical) *P. falciparum* and *P. vivax* samples at low (200) and high (2000[a]) parasite density (parasites/µl) and *Plasmodium* spp. negative samples

Product	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=232)	
Pf only												
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	80.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	93.0	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	98.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9 (231)	0.1
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	93.0	NA	100.0	NA	NA	0.7	NA	0.0	1.3	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	97.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	96.0	NA	100.0	NA	NA	0.0	NA	0.0	0.4	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	94.0 (94/38)[f]	NA	99.0 (99/92)[f]	NA	NA	2.1	NA	1.4	0.4	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	94.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	86.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	94.0	NA	100.0	NA	NA	5.0	NA	1.4	1.7	0.0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	85.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	NA	100.0	NA	NA	0.0 (139)	NA	0.0	0.0	0.1
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	86.0	NA	99.0	NA	NA	2.9	NA	1.4	0.4 (231)	0.1
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	93.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	73.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0
PALUTOP + pf®	5531	ALLDIAG SA	92.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	74.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	77.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	90.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0 (231)	0.1
Pf and Pan												
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	67.0	45.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	85.0	91.4	98.0	100.0	1.3	0.0	1.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	69.0	71.4	96.0	100.0	1.3	0.0	2.0	0.0	0.9	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	88.0	100.0	98.0	100.0	0.5 (399)	0.0	1.0	0.0	1.3	0.1
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	93.0	91.4	98.0	100.0	0.3 (399)	1.4 (138)	1.0	0.0	1.3 (231)	0.3
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	91.0	100.0	99.0	100.0	0.0	0.0	0.5	0.0	3.9	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	85.0	85.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	96.0	97.1	99.0	94.3	0.8	0.7	0.5	2.9	0.9	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	73.0	0.0	100.0	71.4	0.0	0.7	0.0	0.0	1.7	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	93.0	94.3	99.0	97.1	1.3	0.0	0.5	0.0	0.0 (231)	0.1
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	85.0	31.4	98.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	93.0	100.0	99.0	100.0	2.0	0.0	0.5	0.0	3.9	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	92.0	25.7	98.0	91.4	0.8 (399)	3.6 (139)	1.0	4.3	33.2	0.2
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	92.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.4	0.0

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=232)	
Pf and Pv												
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	92.0	97.1	98.0	100.0	1.0	0.0	1.0	1.4 (69)	0.4	0.1
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	75.0	100.0	98.0	100.0	1.0 (399)	0.0 (139)	1.0 (199)	1.5 (68)	0.0 (230)	0.6
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	85.0	91.4	99.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0 (229)	0.3
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	91.0	97.1	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	89.0	100.0	99.0	100.0	1.8	0.0	2.0	0.0	0.0 (231)	0.1
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	93.0	88.6	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	57.1	99.0	100.0	0.0	0.0	0.5 (199)	0.0	0.0 (231)	0.3
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	86.0	2.9	99.0	8.6	22.3	4.3	92.5	7.1	24.6	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	92.0	65.7	100.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	78.0	85.7	100.0	100.0	0.5	0.7	0.0	1.4	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	79.0	88.6	99.0	100.0	39.8	0.0	27.5	0.0	22.9 (231)	0.1
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	85.0	88.6	98.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan												
PALUTOP +4 optima®	5499	ALLDIAG SA	91.0	82.9 (82.9/100)[g]	99.0	100.0 (100/100)[g]	1.3	0.7	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* high parasite density dilution samples were at 5000 parasites/µl rather than 2000

[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

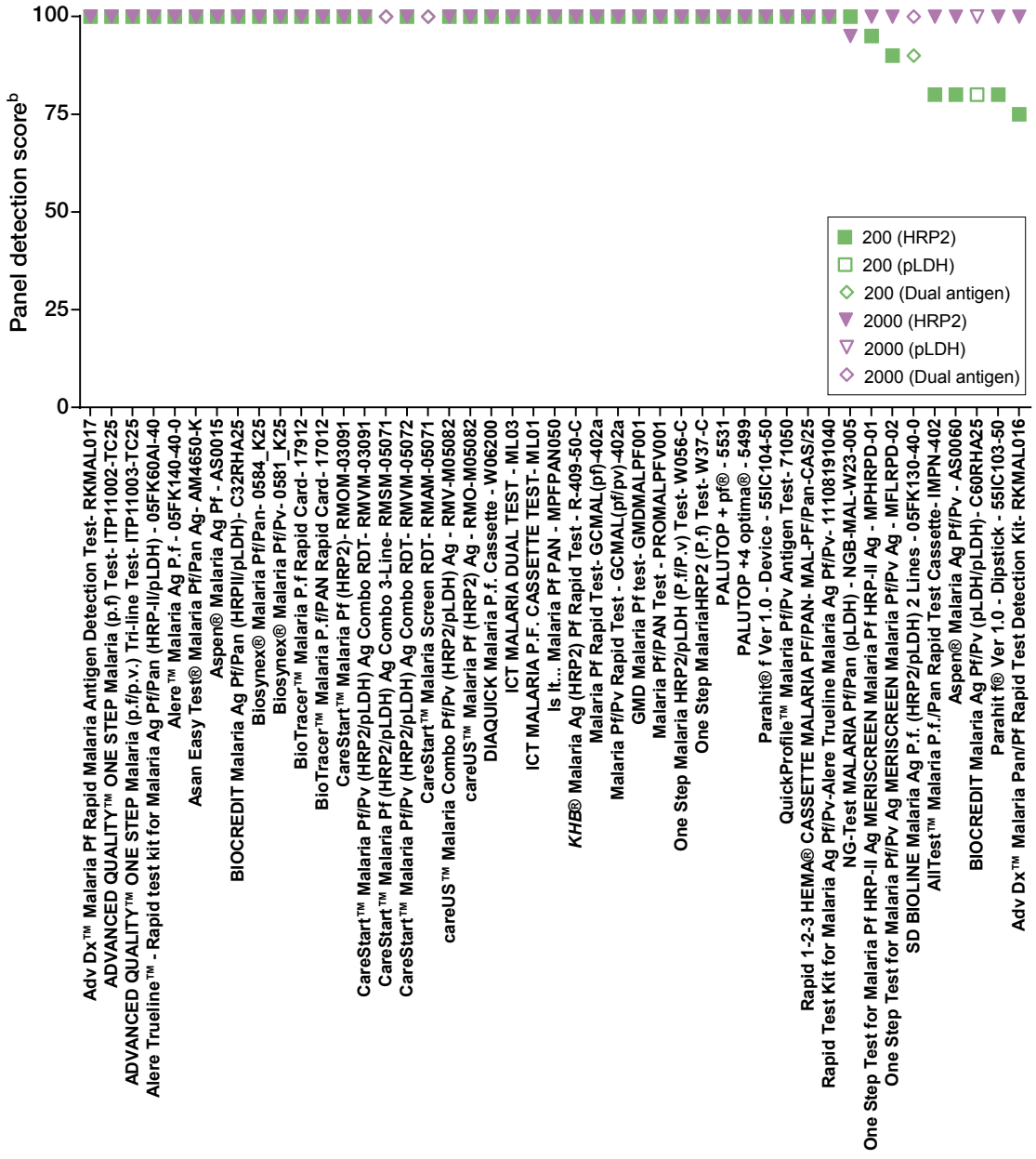
[g] Product PDS shown along with PDS for Pv-pLDH band and Pan-pLDH band, respectively

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

- Only one of two tests met the WHO procurement criterion for detection of *P. falciparum* with Pf-pLDH alone. This test had a PDS of 75%, a false-positive rate of 0% and an invalid rate of 0.6%. However, the test had diminished performance after incubation at 35°C and 45°C (Figs. 22, 23). The PDS in other Pf-pLDH tests in which HRP2 was used to detect Pf on the same test line, ranged from 90% to 94%, however it cannot be distinguished if this performance results from detection of HRP2, Pf-pLDH or both. Tests that can detect *pfhrp2*-deleted parasites are a high priority in malaria-endemic countries with a high prevalence of such parasites *(12, 13, 33, 34)*.
- No consistent pattern was seen in the changing performance of the five compulsorily resubmitted products. The PDS of some of the *P. falciparum* and *P. vivax* tests improved over their results in round 3, while that of others decreased.

Tables 4 and 5 summarize the performance of malaria RDTs against cultured *P. falciparum* parasites, blood containing wild-type *P. falciparum* and *P. vivax* parasites and *Plasmodium* spp.-negative samples. Detailed phase-1 and phase-2 results of product testing are given in Annexes 3 and 4, respectively. The data are shown graphically in Figs. 9–19.

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 but 2 RDTs target HRP2 for falciparum detection. Two products target only pf-pLDH for falciparum detection (RMLM-05071 and C60RHA25). Two products (RMAM-05071 and 05FK130-40-0) target both HRP2 and pf-pLDH on the same line. One product (RMSM-05071) targets both HRP2 and pf-pLDH on separate lines; for this product HRP2 and 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.

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

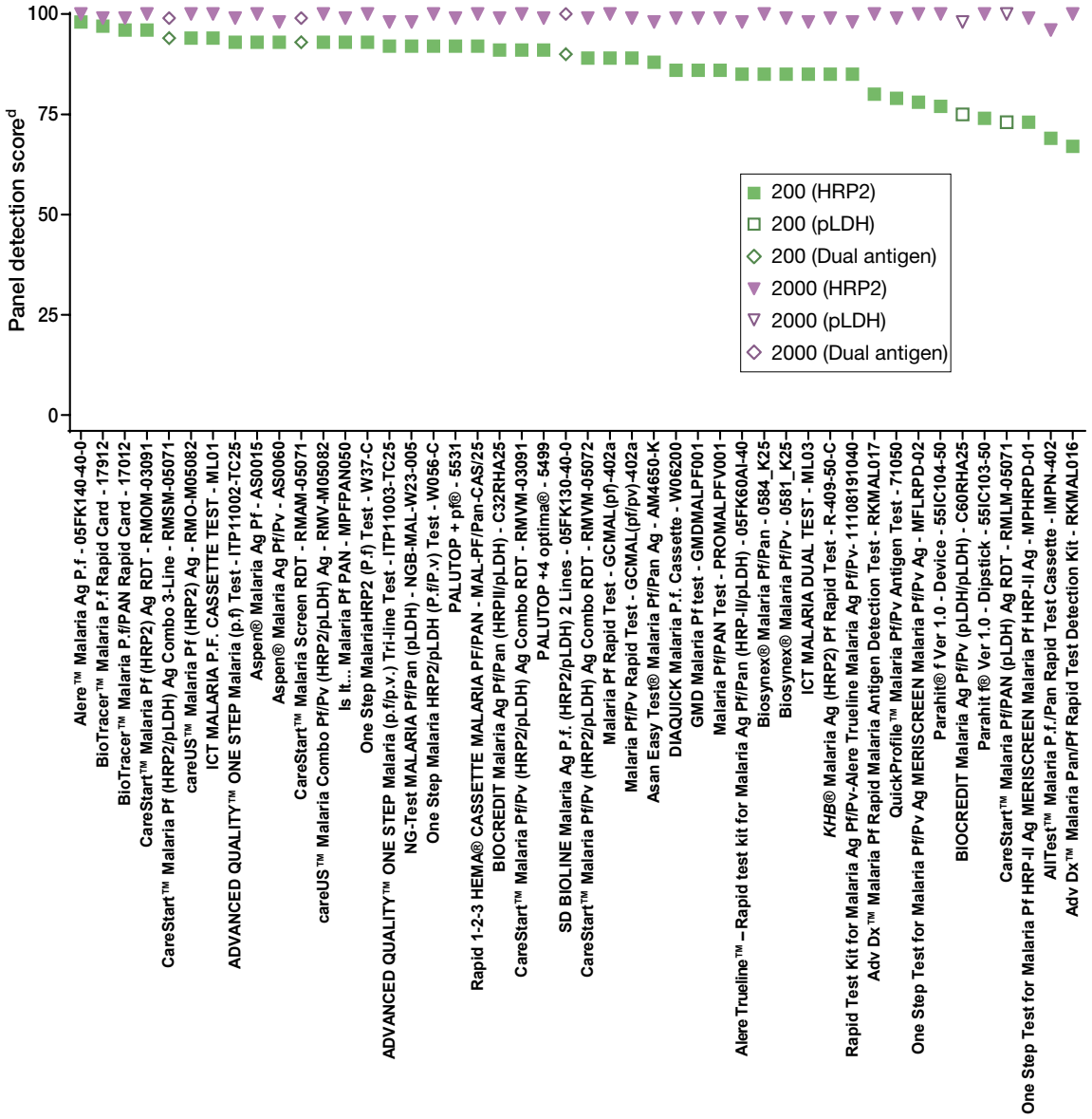
All but one of the products consistently detected 100% of cultured *P. falciparum* parasites at high parasite density (2000 parasites/µL); the PDS of the exception was 95%. The PDS was more variable (75–100%) at low parasite density (200 parasites/µL) (Fig. 9).

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

12.3.1 *P. falciparum* detection

All 46 products in round 7 were designed to detect *P. falciparum*. As in phase 1, all the tests had very high scores at the high parasite density, with a PDS ≥ 96%. Seventeen of the 19 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* high parasite density dilution samples were at 5000 parasites/µL rather than 2000

[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 but 2 RDTs target HRP2 for falciparum detection. Two products target only pf-pLDH for falciparum detection (RMLM-05071 and C60RHA25). Two products (RMAM-05071 and 05FK130-40-0) target both HRP2 and pf-pLDH on the same line. One product (RMSM-05071) targets both HRP2 and pf-pLDH on separate lines; for this product HRP2 and pf-pLDH based results are presented separately in table 5.

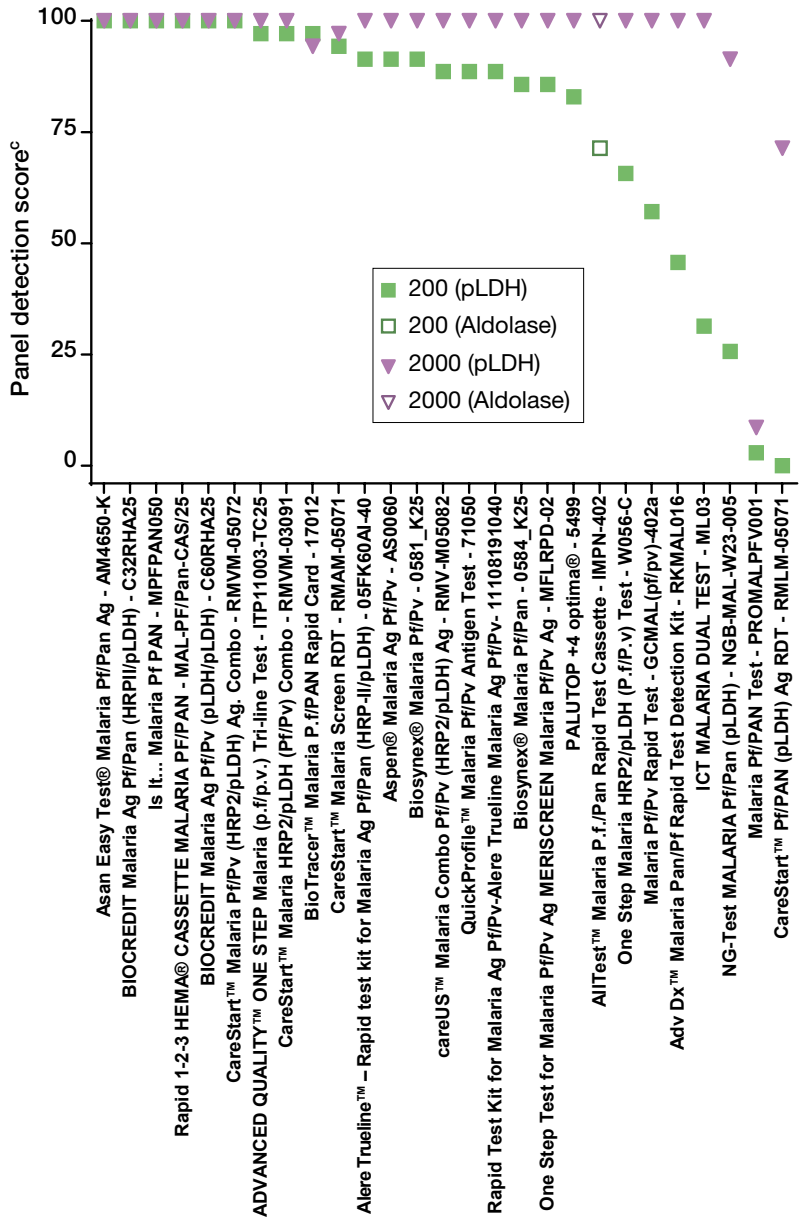
[d] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

Only one of two tests met WHO procurement criteria based on detection of *P. falciparum* with Pf-pLDH alone. This test achieved a PDS of 75%, a false-positive rate of 0% and an invalid rate of 0.6%. The PDS in other Pf-pLDH tests in which HRP2 was used to detect Pf on the same test line, ranged from 90% to 94%, however it cannot be distinguished if this performance results from detection of HRP2, Pf-pLDH or both. Tests that can detect *pfhrp2* gene-deleted parasites are a high priority in malaria-endemic countries with a high prevalence of such parasites *(12, 13, 33, 34)*.

12.3.2 *P. vivax* detection

Fig. 11 shows that 25 of 27 (93%) products designed to detect *P. vivax* consistently detected ≥ 75% at high parasite density (2000 parasites/µL), and 19 (70%) 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), 13 products had a PDS ≥ 90%, and 18 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%.

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.

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

Of the 27 pan-specific and combination tests, 19 (70%) 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.

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

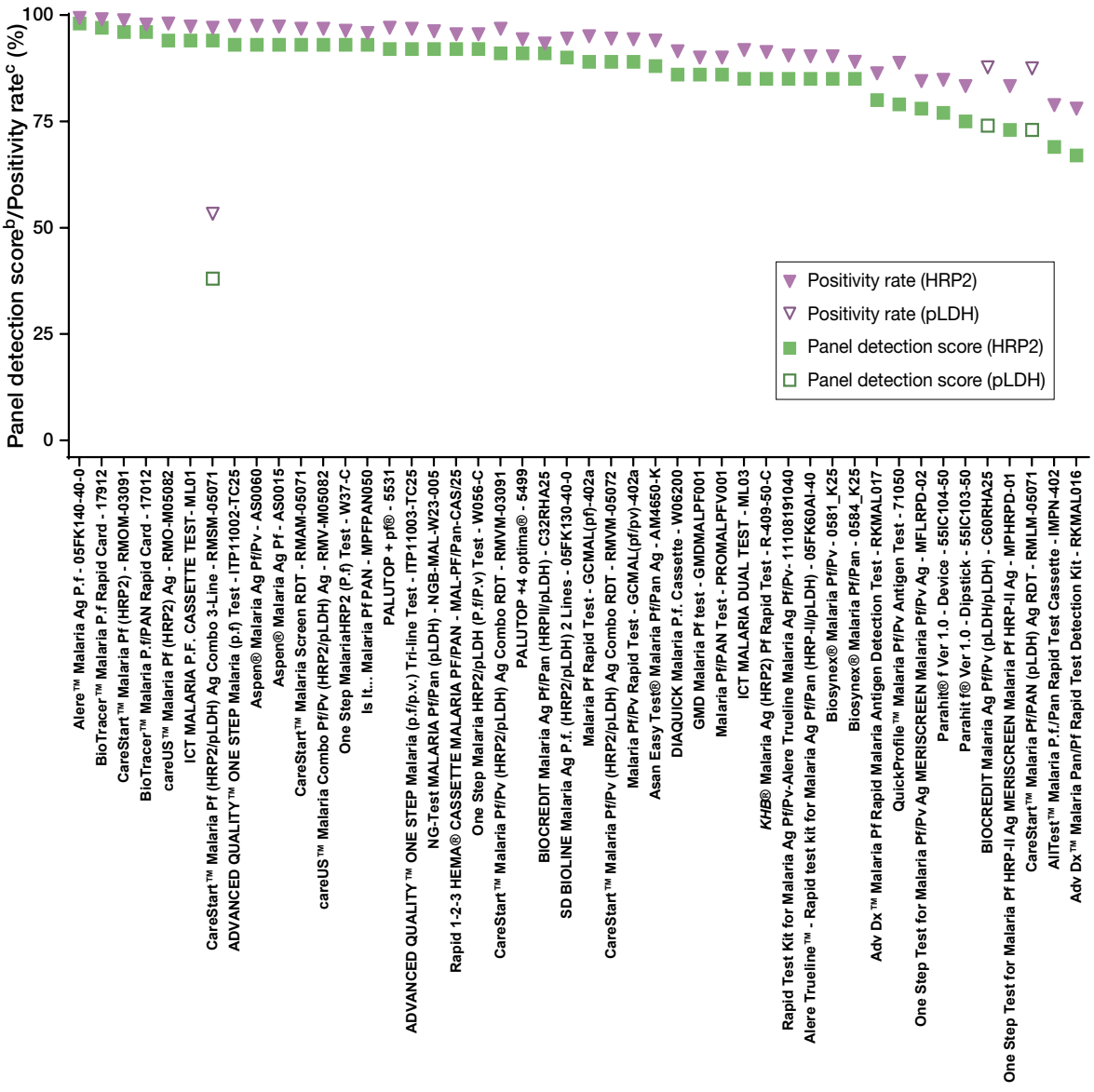
The positivity rate was calculated in addition to the PDS. As expected, the positivity rates were higher than the PDS but mirrored the PDS against wild-type *P. falciparum* and *P. vivax* samples (Figs 12 and 13).

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, $r = 0.75$, $p < 0.001$ for the *P. falciparum* phase-2 panel and $r = 0.82$, $p < 0.001$ for the *P. vivax* panel).

Of the combination RDT products containing a pan test band that gave a positive indication for *P. falciparum* against low-density *P. falciparum* samples, 51.6% (2473/4796) gave positive results on both the *P. falciparum* and pan test

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;

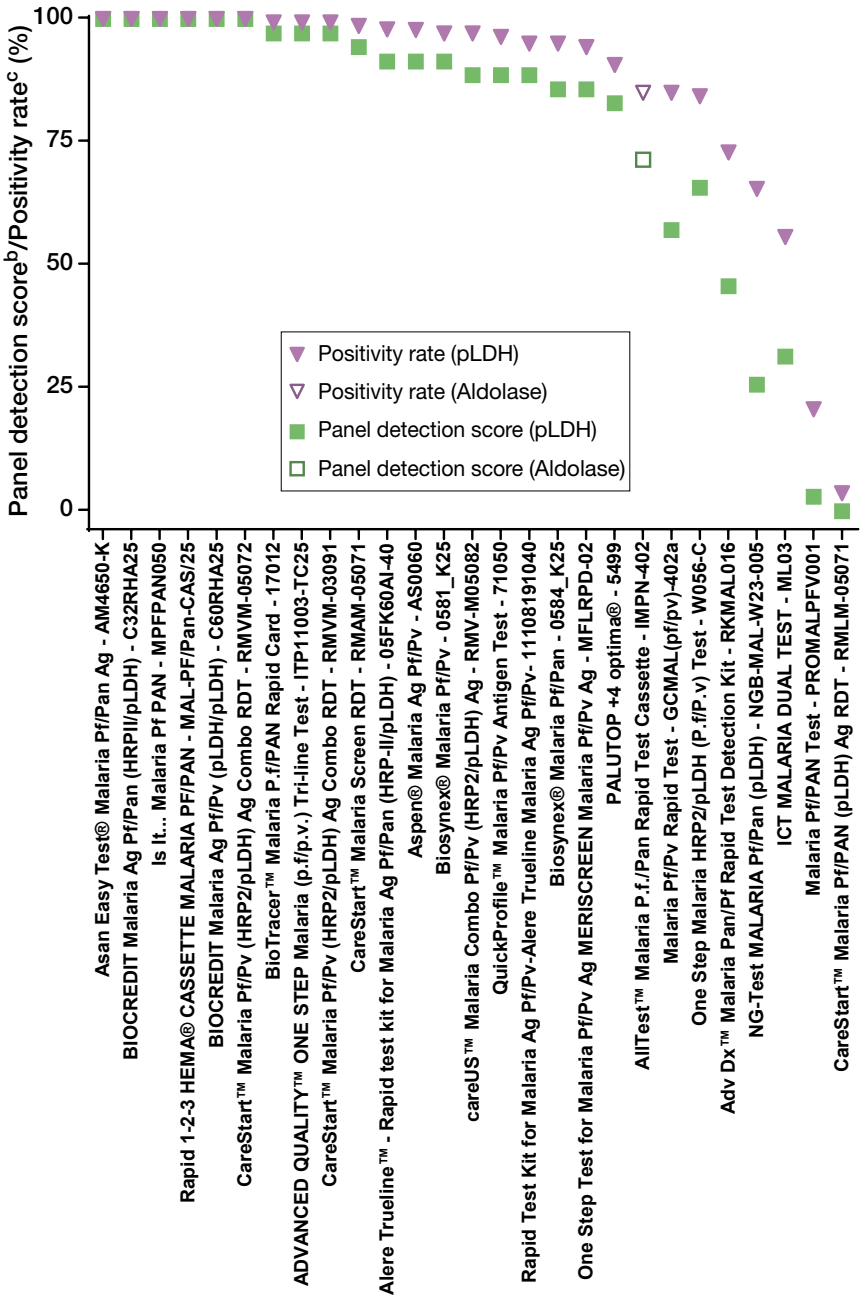
[c] The total number of times a test returned a positive result divided by the total number of times it should have (x100).

bands, and 47.8% (2292/4796) were positive only on the *P. falciparum* test band. A small proportion (0.6%, 31/4796) were positive only on the pan test band.

When the pan test band in the combination products was positive, the intensity of the band was the same as the *P. falciparum* test band in 11.2% of tests, while 33.0%, 39.1% and 16.7% of the pan tests bands were one, two and three intensities lower than the corresponding *P. falciparum* test bands, respectively. Only 0.1% of tests had a pan band intensity larger than the corresponding *P. falciparum* test band.

When tested at low parasite density, none of the tests achieved 75% with a band intensity > 2 for *P. falciparum* or *P. vivax*, although 12 achieved at least 50% with this intensity for *P. falciparum* and 1 for *P. vivax*.

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;

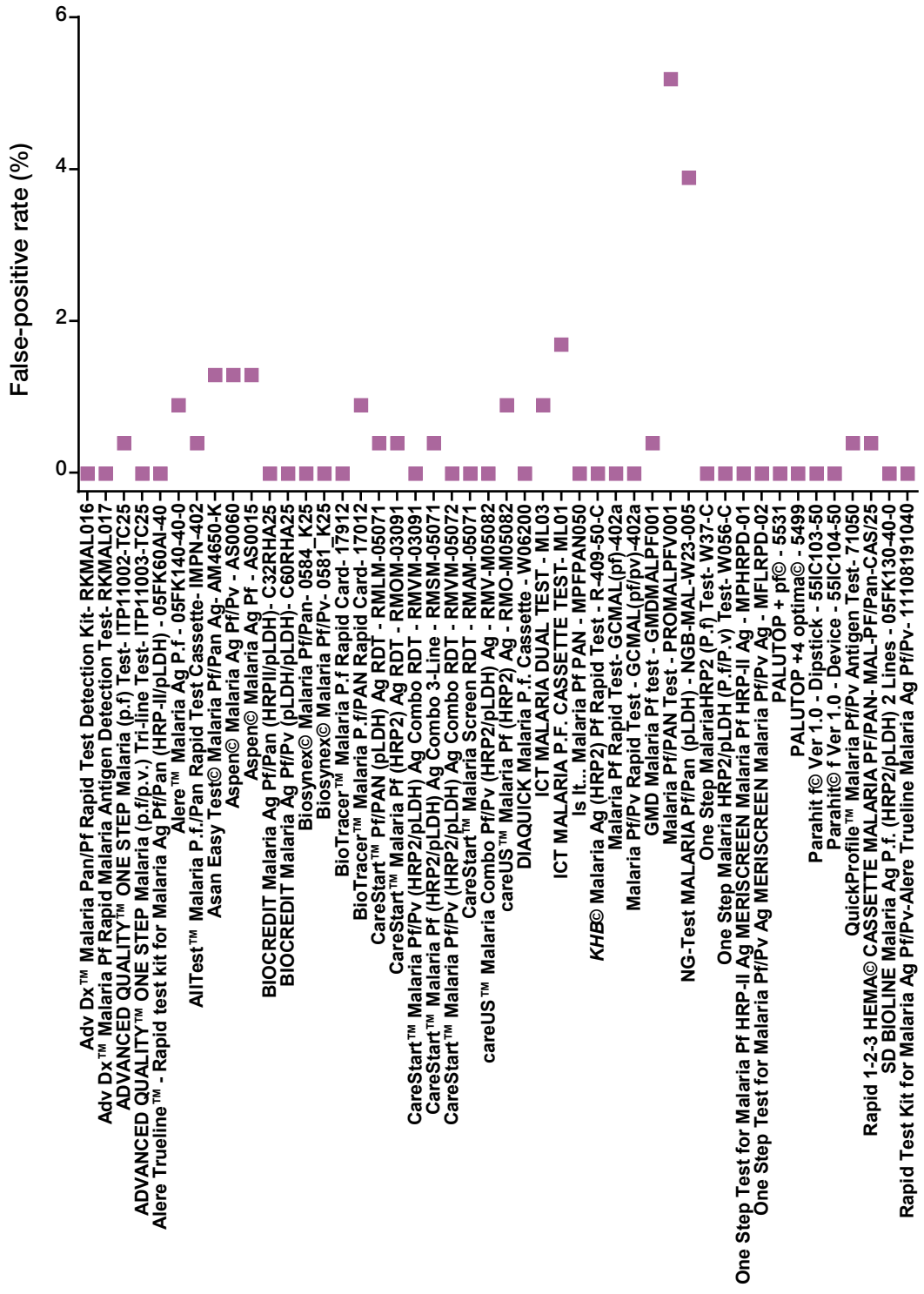
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive;

[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

None of the products had a false-positive rate > 10% with 52 clean-negative samples of the *P. falciparum* test line (Fig. 14); three products had false-positive rates > 10% with pan or *P. vivax* test lines (Fig. 15). Fifteen products had false-positive rates > 5.6% (for one or both lots), against samples containing immunological factors. The rates of 9 of these were 5.6–7.4%, and those of a further six were 11.1–24.1% in both lots. These rates are worse than those in round 6 but similar to those in previous rounds. False positivity was seen predominantly for samples containing immunological factors (seven of the eight instances of false positivity > 10%).

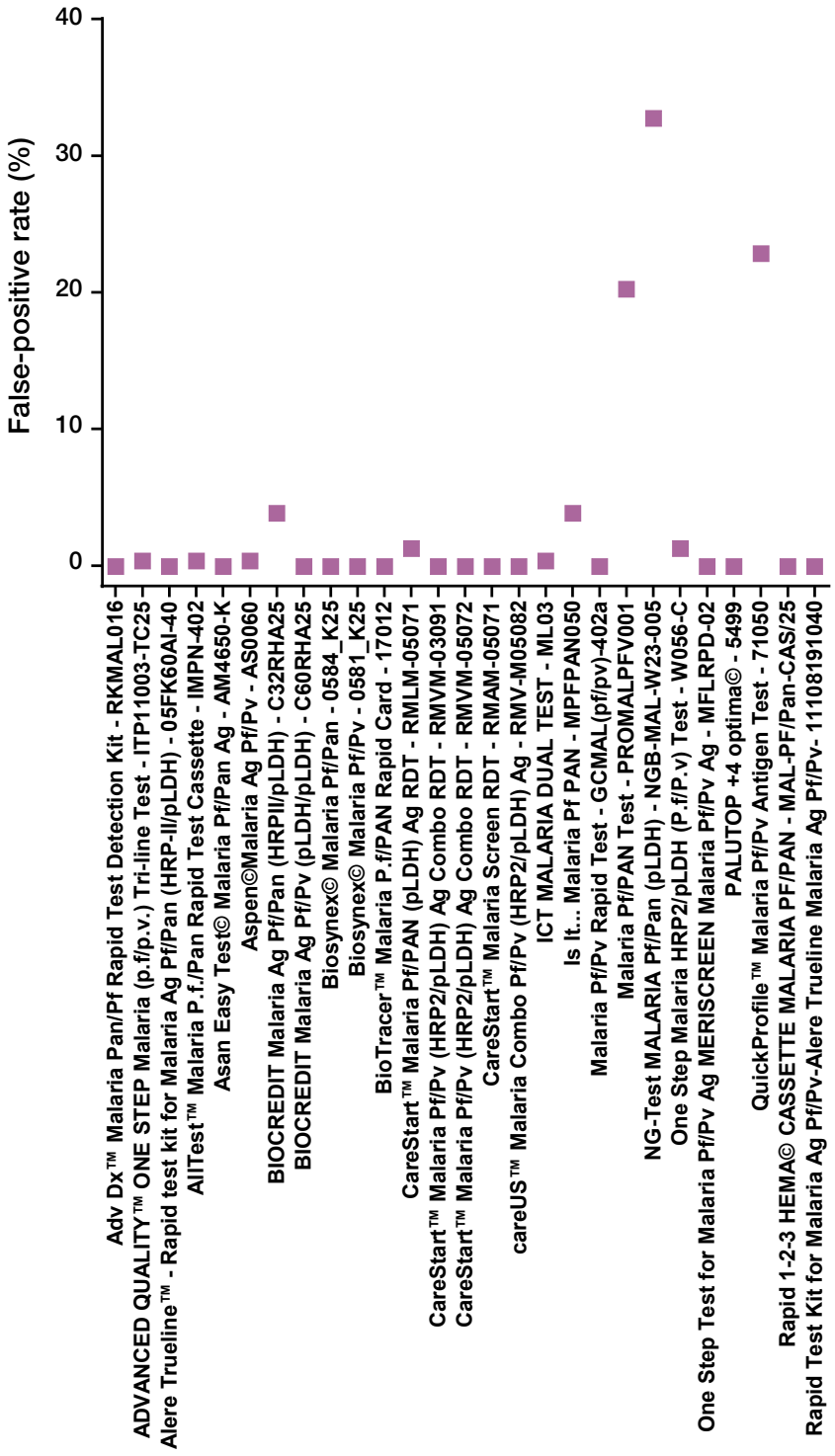
Figure 14: Phase-2 *P. falciparum* (*P. falciparum* test line) false-positive rate against clean-negative samples[a]



[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.

The false-positivity rates for samples containing non-*Plasmodium* spp. agents were similar to those in round 6. In only four products was the false-positivity rate > 3.3%, and only one had a false positivity rate > 10% (10% and 13% in each of the two lots); three products had false-positivity rates of 6.7% for one or both lots. False positivity was seen against all four of the samples of infections pathogens used: schistosoma, leishmaniasis, Chagas disease and dengue.

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



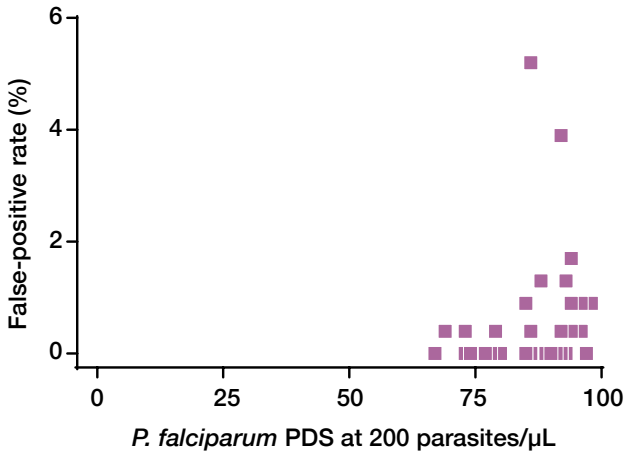
[a] Phase-2 evaluation panel included 100 *Plasmodium* spp.-negative samples of which 52 were clean negatives, from healthy volunteers with no known current illness or blood abnormality.

Only 21 samples contained non-*Plasmodium* infectious agents and 27 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).

Products were assessed for false-positivity rates for species that they were not designed to detect (Tables A4.4 and A4.5). Overall, the rates were low; only two combination products showed > 10% false positivity for a non-*P. falciparum* infection when tested against samples of *P. falciparum* at 200 or 2000 parasites/µL.

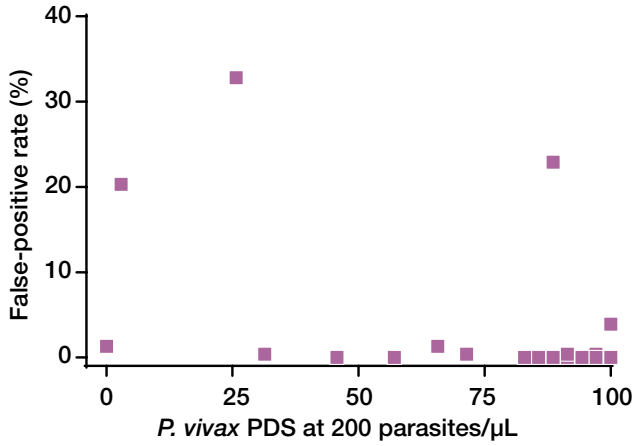
There was no clear trend of higher false-positive rates in tests with higher PDS, indicating no clear association between the sensitivity and specificity of the tests at these detection thresholds (Figs 16 and 17).

Figure 16: Phase-2 *P. falciparum* false-positive rate[a] versus *P. falciparum* 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.

Figure 17: Phase-2 *P. vivax* false-positive rate[a] versus *P. vivax* panel detection score[b] at low parasite density (200 parasites/µL)



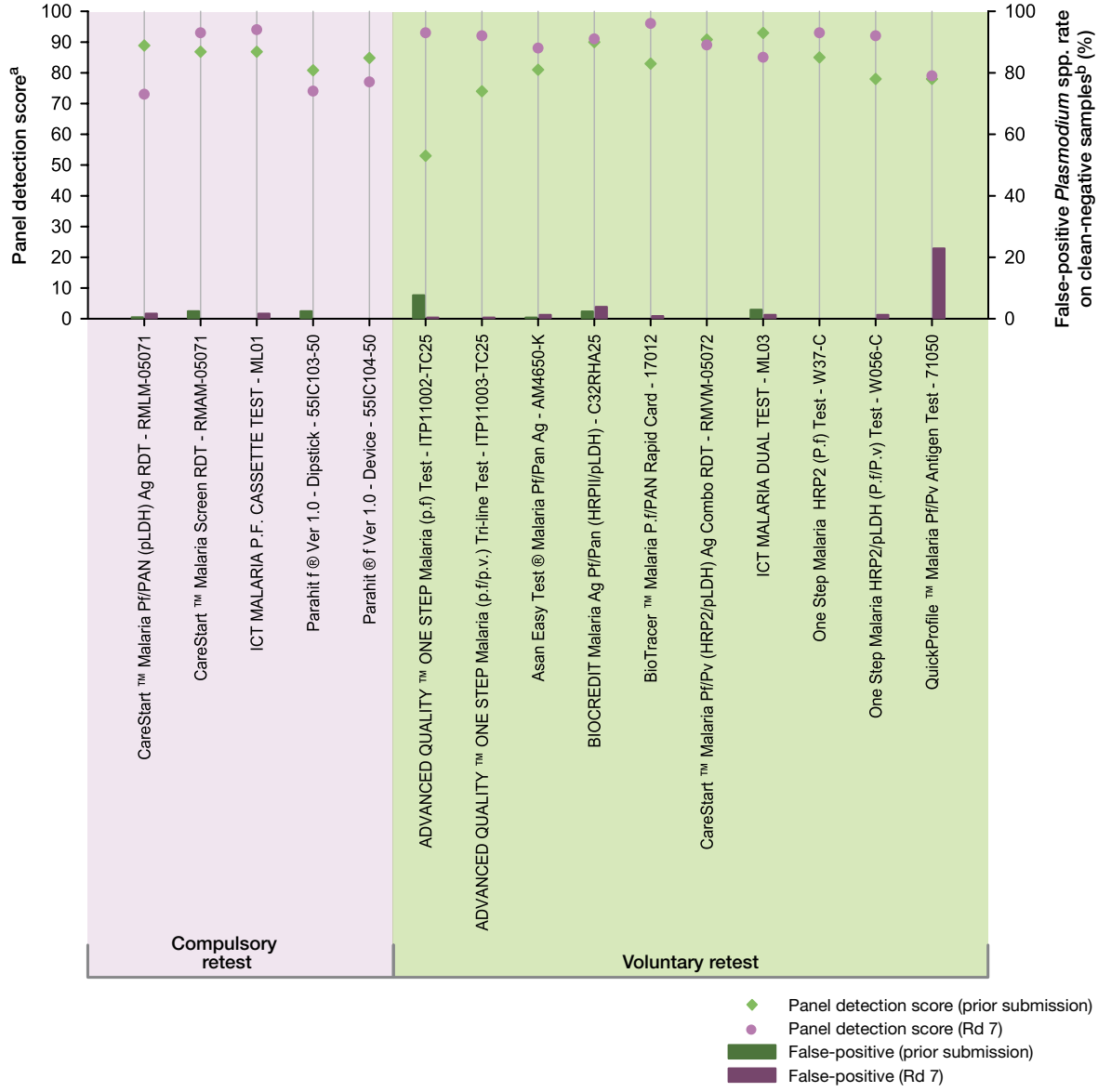
[a] False-positive rate is for clean negatives only.
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

12.4. Performance of resubmitted products

Of the 46 products in round 7, 15 (33%) had been evaluated previously. For six of the resubmissions, this was the second testing, and nine 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.

The change in PDS between the two rounds varied for the five products that had not been tested since round 3 (compulsory resubmissions): two had improved performance against *P. falciparum* (increases of 6 and 7 percentage points), and three showed worse performance (decreases of 7, 8 and 11 percentage points). The changes in the two pan-detecting products in their ability to detect *P. vivax* differed from those in round 3: the PDS of one increased by 5 percentage points, while that of the other dropped from 91% in round 3 to 0 in round 7.

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

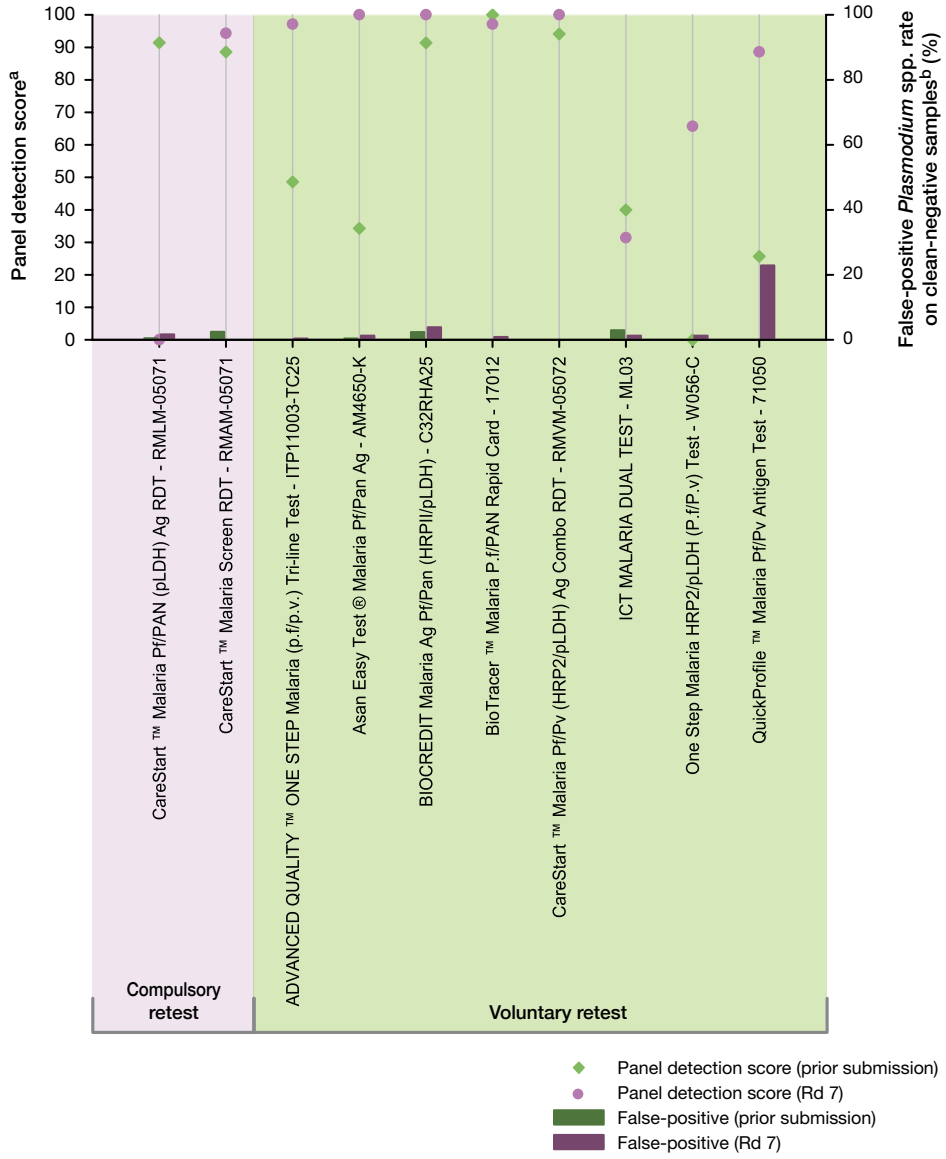


[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
[b] Clean-negative blood samples from healthy volunteers with no known current illness or blood abnormality.

For the 10 products that were voluntarily resubmitted for testing, no significant correlation was found between the PDS for *P. falciparum* at lower parasite density in consecutive submissions (Spearman rank correlation, $r = -0.30$, $P = 0.405$). The median change in detection of *P. falciparum* was +7.5% (range, –8.0 to 40.0%), which was almost significantly different from zero (Wilcoxon signed rank test, $P = 0.052$). Most of the products (8/10) detected *P. vivax*, and detection of this parasite improved overall (median change, 28.6%; range, –8.6 to 65.7%), which was almost statistically significant (Wilcoxon signed rank test, $P = 0.058$). No statistically significant correlation was found between the PDS of consecutive submissions against *P. vivax* at lower parasite density (Spearman rank correlation, $r = 0.503$, $P = 0.20$).

On re-testing, approximately half of the resubmitted products (7/15) showed no change or an improvement in their false-positivity rate against clean negative samples; the median change in false-positivity rate was +0.4%. Most of the changes on re-testing were small (< 2.5%), except for two products, in which the false-positivity rate decreased by 7.3% for one product and increased by 22.9% for another. Both of these products were voluntarily resubmitted for testing in Round 7.

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. Continuous in vitro culture of a wild-type *P. vivax* sample is difficult, largely because of selective invasion of reticulocytes by the parasite. Round 7 was the second in which the stability of test lines to detect non-*P. falciparum* parasites was 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 obtainable 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 obtainable 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*

All of the 19 *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. One *P. falciparum*-only detecting product had a line that detected *P. falciparum* pLDH (in addition to an HRP2 line). Both lines were heat stable.

Of the 27 combination tests, 25 had an HRP2-detecting line. Of these, 24 tests were heat stable against a cultured *P. falciparum* sample. The 25th showed slight deterioration after 2 months' storage at 45 °C. One of the 24 heat-stable products showed a slight loss in detection when stored at 35 °C but not at 45 °C. The two combination tests with only pLDH-detecting lines for *P. falciparum* both showed some heat instability: one with a slight decline in performance at 35 °C and then again at 45 °C, and the second with a major decrease in performance at 35 °C and then again at 45 °C.

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 (i.e. scoring at least 28/30) 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. The stability of pan-pLDH-detecting test lines was much poorer than that of HRP2-detecting test lines (Figs 20–25).

13.3. *Plasmodium vivax*

Testing of the heat stability of *P. vivax*-detecting lines using a *P. vivax* clinical sample was introduced in round 6. Many (11/14) of the combination RDTs with a pan-LDH test line were heat stable after 2 months' storage at 45 °C when tested against a wild-type *P. vivax* sample. Two of the 11, however, showed some variation in performance under other conditions: one had slightly poorer performance at baseline and after storage at room temperature, and the other had very poor performance after storage at 35 °C. Of the three tests that did not detect 100% of samples after storage at 45 °C, two showed 100% detection at baseline but some decrease after storage at 35 °C and 45 °C (one with only a slight decrease and the other with a more significant decrease). The third of the three tests performed very poorly at baseline (only 2 of 8 samples detected) and did not detect any samples after storage at any temperature.

The *P. vivax* pLDH line appeared to be more stable, 11 of 13 being heat stable under all testing conditions and a further one showing only a slight decrease in detection at 35 °C and 100% detection at 45 °C. The exception was a product in which the *P. vivax* pLDH line did not detect any of the *P. vivax* samples at baseline or after storage at room temperature and only slightly better performance after incubation with one of eight samples detected after storage at 35 °C and three of eight samples detected after storage at 45 °C (Figs 26–29).

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

Table 6a: Heat stability testing results for 46 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (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																		
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	30 (30/30)[b]	30 (30/30)[b]	30 (30/30)[b]	30 (30/30)[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
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	30	30	30	29 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
PALUTOP + pf®	5531	ALLDIAG SA	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	30	30	30	29 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Pf and Pan																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	30	29	30	30	0	0	0	0	10	10	10	10	10	10	10	10
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	30	30	30	30	14	11	21	10	10	10	10	10	10	10	10	10
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	30	30	30	30	0	3	0	5	10	10	10	10	9	10	10	10
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	30	30	30	30	23	26	15	3	10	10	10	10	10	10	10	10
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	30	30	30	30	15	25	27	30	10	10	10	10	10	10	10	10
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	30	30	30	30	24	18	8	2	10	10	10	10	10	10	10	10
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	30	30	30	29	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	29	30	21	10	10	10	10	10	10	10	10
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	30	30	29	28	0	0	2	0	10	10	10	10	10	9	10	10
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	30	30	30	30	30	28	30	30	10	10	10	10	10	10	10	10
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	30	30	30	30	1	0	1	4	10	10	10	10	9	10	10	10

(continued)

Table 6a: Heat stability testing results for 46 malaria RDTs on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (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) 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			
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	30	30	28	30	28	29	28	28	10	10	10	10	10	10	10	10
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	30	30	30	30	16	15	26	20	10	10	10	10	10	10	10	10
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	30	30	30	30	0	5	0	10	10	10	10	10	10	10	10	10
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	28	30	26	17 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	30	30	30	30	NA	NA	NA	NA	10	10	10	9 (9)	NA	NA	NA	NA
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	30	30	30	30	30	30	30	30	10	10	10	10	10	10	10	10

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 27 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]

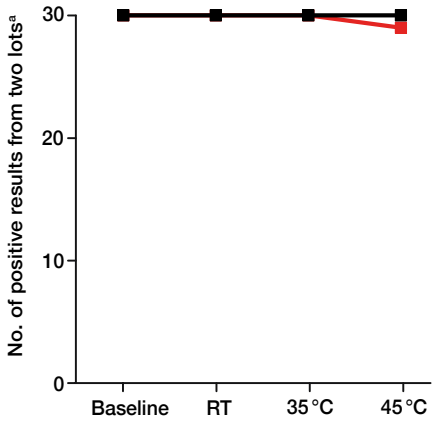
Product	Product code	Manufacturer	Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (pan line)				Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (pan line)			
			200 parasites/µL				200 parasites/µL				2000 parasites/µL				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																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	NA	NA	NA	NA	8	7	4	8	NA	NA	NA	NA	4	4	4	4
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	NA	NA	NA	NA	7	7	8	8	NA	NA	NA	NA	4	4	4	4
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	NA	NA	NA	NA	8	8	7	7	NA	NA	NA	NA	4	4	4	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	3	4	4
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	NA	NA	NA	NA	8	8	8	8	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	NA	NA	NA	NA	2	0	0	0	NA	NA	NA	NA	3	1	4	2
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	NA	NA	NA	NA	8	7	8	8	NA	NA	NA	NA	4	4	4	4
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	NA	NA	NA	NA	8	8	7	5	NA	NA	NA	NA	4	4	4	4
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	3 (3)	NA	NA	NA	NA
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	3 (3)	NA	NA	NA	NA
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	1	3	NA	NA	NA	NA	0	0	1	0	NA	NA	NA	NA
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	8	8	7	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	8	8	8	8	8	8	8	8	4	4	4	4	4	4	4	4

NA, not applicable

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

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

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

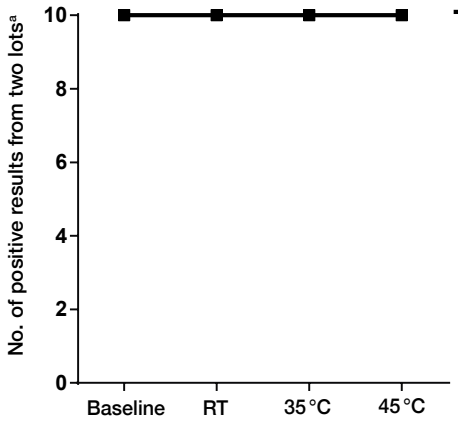


Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test - RKMAL017
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test - ITP11002-TC25
Alere™ Malaria Ag P.f - 05FK140-40-0
Aspen© Malaria Ag Pf - AS0015
BioTracer™ Malaria P.f Rapid Card - 17912
CareStart™ Malaria Pf (HRP2) Ag RDT - RMOM-03091
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - RMSM-05071
careUS™ Malaria Pf (HRP2) Ag - RMO-M05082
DIAQUICK Malaria P.f. Cassette - W06200
ICT MALARIA P.F. CASSETTE TEST - ML01
KHB© Malaria Ag (HRP2) Pf Rapid Test - R-409-50-C
GMD Malaria Pf test - GMDMALPF001
One Step MalariaHRP2 (P.f) Test - W37-C
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag - MPHRPD-01
PALUTOP + pf© - 5531
Parahit© f Ver 1.0 - Device - 55IC104-50
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines - 05FK130-40-0

Malaria Pf Rapid Test - GCMAL(pf)-402a
Parahit f© Ver 1.0 - Dipstick - 55IC103-50

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

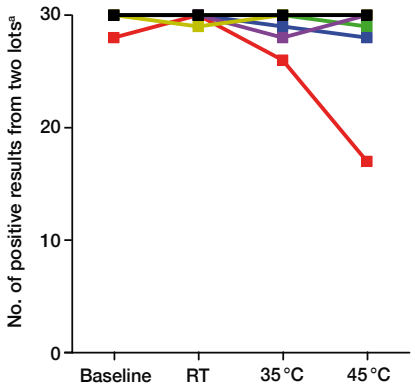
Figure 21: Heat stability of *P. falciparum*-specific test line of *P. falciparum*-only tests against a high-density *P. falciparum* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test - RKMAL017
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test - ITP11002-TC25
Alere™ Malaria Ag P.f - 05FK140-40-0
Aspen© Malaria Ag Pf - AS0015
BioTracer™ Malaria P.f Rapid Card - 17912
CareStart™ Malaria Pf (HRP2) - RMOM-03091
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - RMSM-05071
careUS™ Malaria Pf (HRP2) Ag - RMO-M05082
DIAQUICK Malaria P.f. Cassette - W06200
ICT MALARIA P.F. CASSETTE TEST - ML01
KHB© Malaria Ag (HRP2) Pf Rapid Test - R-409-50-C
Malaria Pf Rapid Test - GCMAL(pf)-402a
GMD Malaria Pf test - MDMALPF001
One Step MalariaHRP2 (P.f) Test - W37-C
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag - MPHRPD-01
PALUTOP + pf© - 5531
Parahit f© Ver 1.0 - Dipstick - 55IC103-50
Parahit© f Ver 1.0 - Device - 55IC104-50
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines - 05FK130-40-0

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

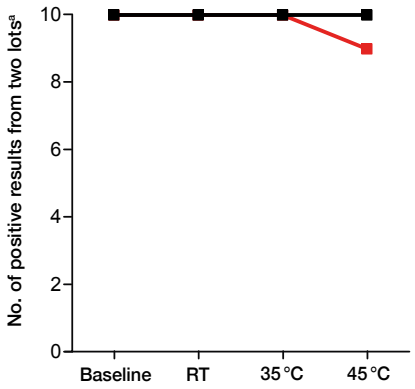
Figure 22: Heat stability of *P. falciparum*-specific test line in combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test - ITP11003-TC25
Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
Asan Easy Test® Malaria Pf/Pan Ag - AM4650-K
Aspen® Malaria Ag Pf/Pv - AS0060
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C32RHA25
Biosynex® Malaria Pf/Pv - 0581_K25
BioTracer™ Malaria P.f/PAN Rapid Card - 17012
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-05072
CareStart™ Malaria Screen RDT - RMAM-05071
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
ICT MALARIA DUAL TEST - ML03
Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
Malaria Pf/PAN Test - PROMALPFV001
NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
PALUTOP +4 optima® - 5499
QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN - MAL-PF/Pan-CAS/25
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv - 11108191040
Biosynex® Malaria Pf/Pan - 0584_K25
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
Is It... Malaria Pf PAN - MPFPAN050
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25

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

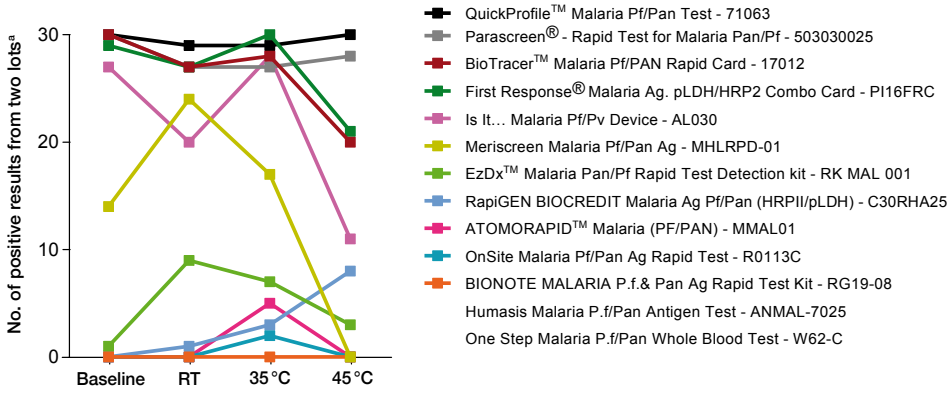
Figure 23: Heat stability of *P. falciparum*-specific test line in combination tests against a high-density *P. falciparum* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test - ITP11003-TC25
Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
Asan Easy Test® Malaria Pf/Pan Ag - AM4650-K
Aspen® Malaria Ag Pf/Pv - AS0060
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C32RHA25
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
Biosynex® Malaria Pf/Pan - 0584_K25
Biosynex® Malaria Pf/Pv - 0581_K25
BioTracer™ Malaria P.f/PAN Rapid Card - 17012
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-05072
CareStart™ Malaria Screen RDT - RMAM-05071
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
ICT MALARIA DUAL TEST - ML03
Is It... Malaria Pf PAN - MPFPAN050
Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
Malaria Pf/PAN Test - PROMALPFV001
NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
PALUTOP +4 optima® - 5499
QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN - MAL-PF/Pan-CAS/25
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv - 11108191040

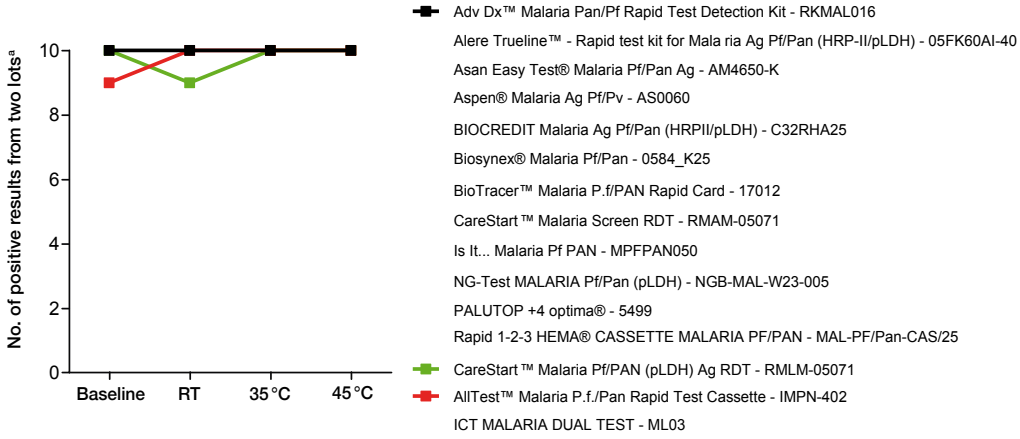
[a] Maximum score is 10 (5 tests x 2 lots)

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.



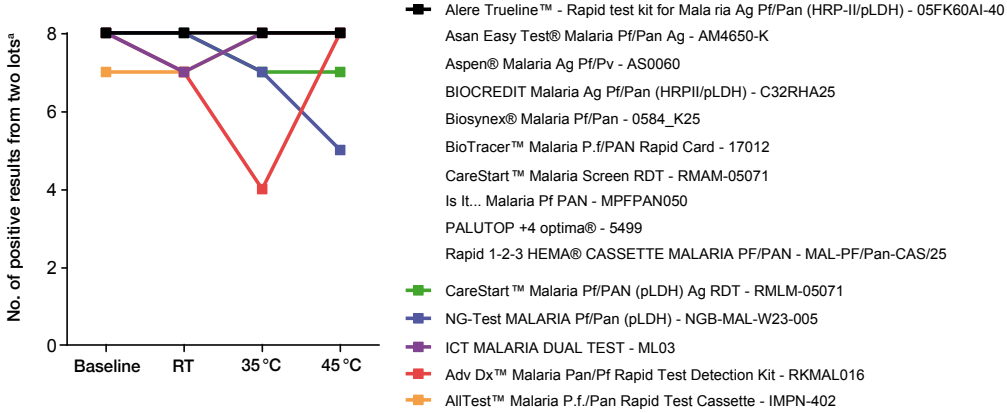
[a] Maximum score is 30 (15 tests x 2 lots)

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.



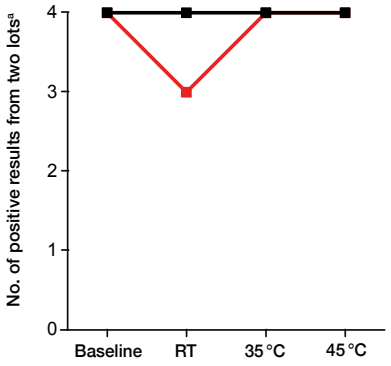
[a] Maximum score is 10 (5 tests x 2 lots)

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)

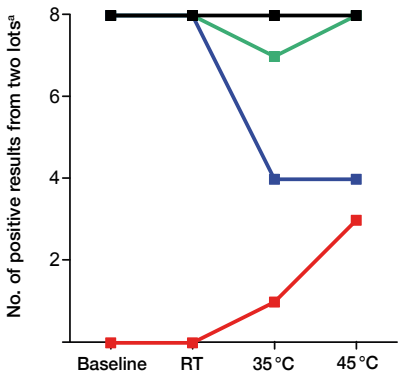
Figure 27: Heat stability of pan line of combination tests against a high-density *P. vivax* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation



- Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
- Alere Trueline™ - Rapid test kit for Mala ria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
- AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
- Asan Easy Test® Malaria Pf/Pan Ag - AM4650-K
- Aspen® Malaria Ag Pf/Pv - AS0060
- Biosynex® Malaria Pf/Pan - 0584_K25
- BioTracer™ Malaria P.f/PAN Rapid Card - 17012
- CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
- CareStart™ Malaria Screen RDT - RMAM-05071
- ICT MALARIA DUAL TEST - ML03
- Is It... Malaria Pf PAN - MPFPAN050
- NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
- Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN - MAL-PF/Pan-CAS/25
- PALUTOP +4 optima® - 5499
- BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C32RHA25

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

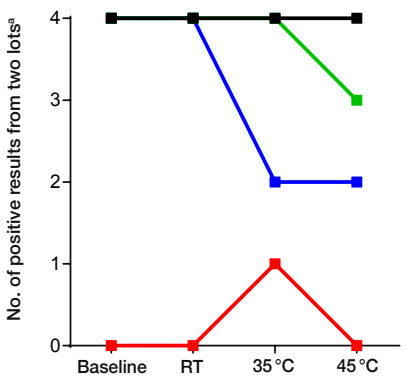
Figure 28: Heat stability of *P. vivax*-specific test line in combination tests against a low-density *P. vivax* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test - ITP11003-TC25
- BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
- Biosynex® Malaria Pf/Pv - 0581_K25
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
- careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
- Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
- One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
- One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
- PALUTOP +4 optima® - 5499
- QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
- Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv - 11108191040
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-05072
- Malaria Pf/PAN Test - PROMALPFV001

[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 - ITP11003-TC25
- Biosynex© Malaria Pf/Pv - 0581_K25
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
- careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
- One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
- One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
- PALUTOP +4 optima© - 5499
- QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
- Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv - 11108191040
- BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
- Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-05072
- Malaria Pf/PAN Test - PROMALPFV001

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

14. DESCRIPTION OF EASE OF USE, ANOMALIES, LABELLING AND INSTRUCTIONS FOR USE

14.1. Ease of use

After becoming proficient in using a product, two technicians submitted a joint agreed assessment of its 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. The assessment did 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 by manufacturer in many products. Procurement decisions should be based on which transfer devices are best suited for the intended users, which 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 product selection (Annex S2, Table AS2.1).

14.2. Anomalies

In round 7, technicians regularly recorded anomalies from 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 in which specific anomalies were observed and the frequency of tests with an anomaly in 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. In round 7, 33 of the 46 products had between one and five different types of anomaly; in 13 products, no anomaly was seen (Table 8, Fig. 30). Incomplete clearing and red background (not obscuring test lines) were the most common anomalies, seen in 48% and 24% of products, respectively. Incomplete migration, failed migration and a red background obscuring the test lines were seen next most often, in 15%, 11% and 11% of products, respectively. In most (31) of the 33 products with anomalies, they were found in < 1% of the tests; in two products, anomalies occurred in 1.4% of tests (Table 8). This rate is much lower than that in round 6, when all products had between one and six anomalies and approximately half had a frequency > 2%.

14.3. Labelling and instructions for use

Adherence to a list of recommendations for instructions for use and product labelling were assessed for the first time in Round 7. Figs 31–38 show the percentages of products that adhered to the recommendations, grouped by theme.

Generally good adherence was found to the recommendations for labelling of the main package (Fig. 31) and the device (Fig. 32), with exceptions in the guidance on storage conditions and the inclusion of appropriate warning labels. Labelling of the buffer bottle (Fig. 33) and accessories (Figs 34–36) met only a few recommendations (see below). The instructions for use were highly variable, and many recommendations, including critical ones, were not met.

An important area of divergence from the recommendations was for laboratory safety. For example, none of the blood transfer devices carried labels indicating that they were for single use only, and 59% of lancet packages had no indication that those with damaged packaging should not be used (Fig. 35). The instructions for use of less than 10% of products advised disposal of tests in biohazard waste containers, and those of less than 20% advised disposal of lancets in sharps containers (Fig. 38). Only 26% of the instructions advised that a new pair of gloves should be used at each step (Fig. 38).

Important omissions were also found in basic product information: 28% of instructions for use did not mention that some necessary materials were not included in the kit (Fig. 37), and 33% did not list limitations of product. In terms of product specifications, nearly all the instructions listed the diagnostic sensitivity and specificity of the product, but few mentioned analytical sensitivity or specificity or gave information on parasite densities and reference methods (Fig. 37). Adherence to recommendations for describing procedures was also variable. While all gave good guidance on the interpretation of line combinations for positive results, fewer than half advised that a faint line should be considered a positive result (Fig. 38).

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

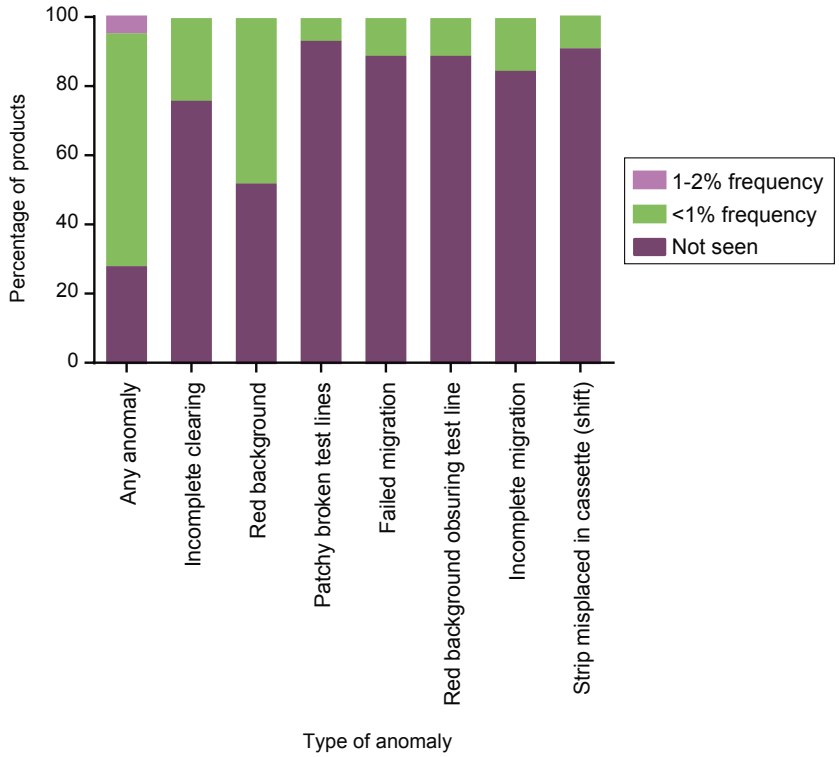


Figure 31: Adherence to box labelling recommendations

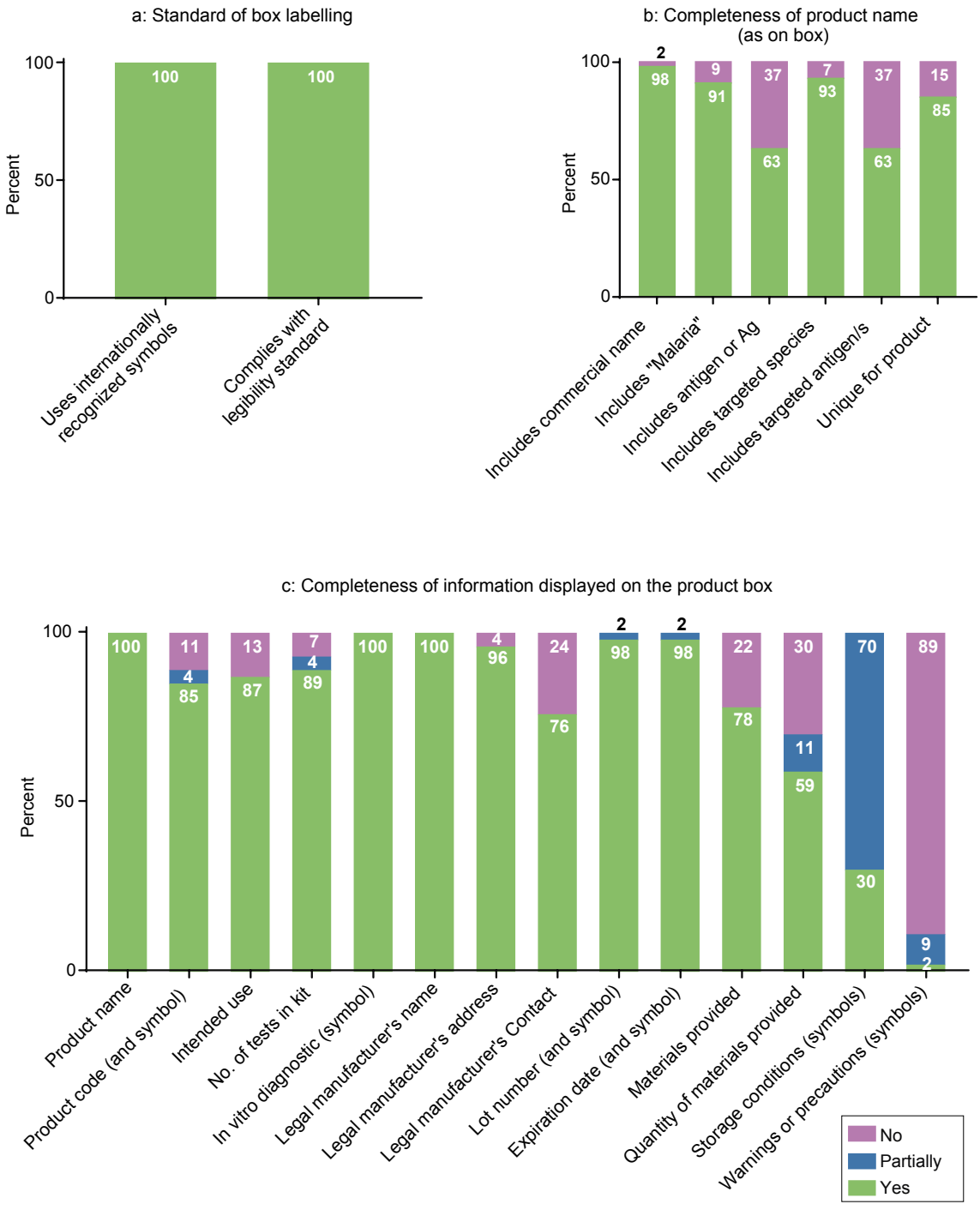


Figure 32: Adherence to cassette labelling recommendations

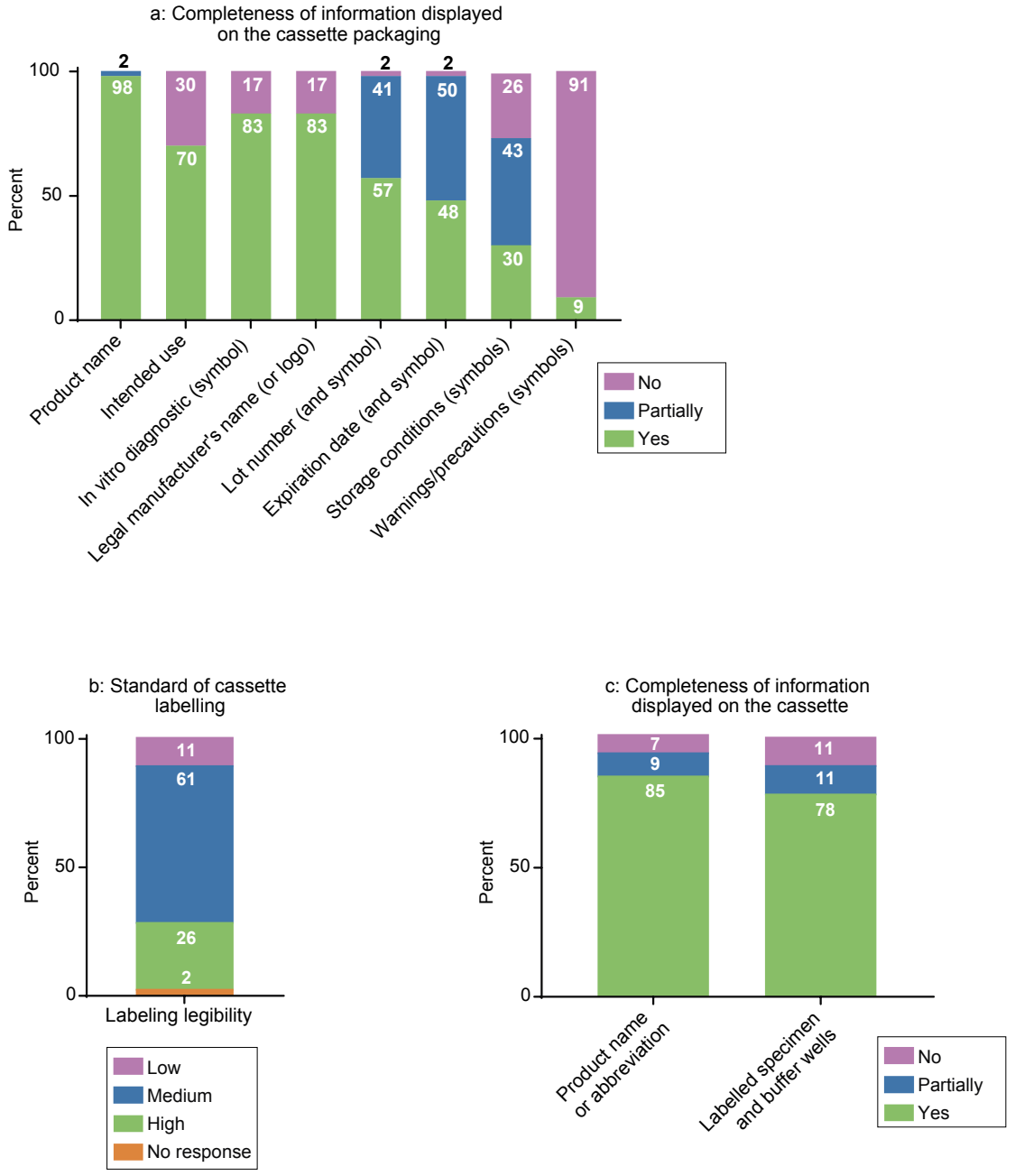


Figure 33: Adherence to buffer bottle labelling recommendations

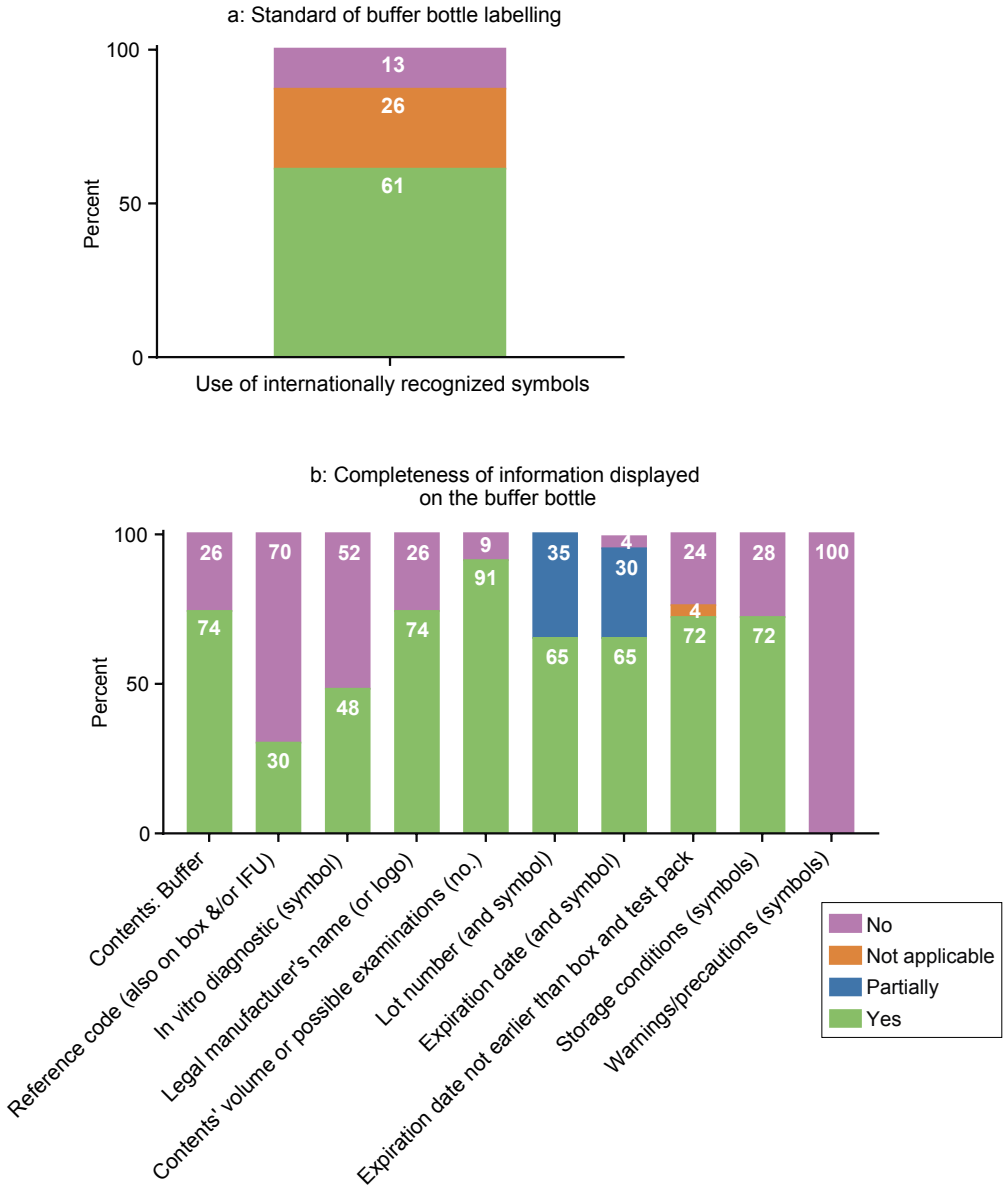


Figure 34: Accessory labelling – use of internationally recognized symbols

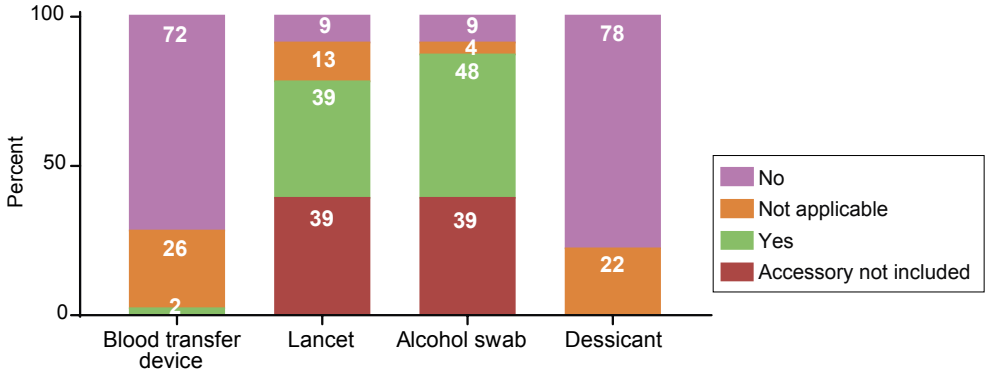


Figure 35: Completeness of information on accessory packaging – blood transfer device and lancet

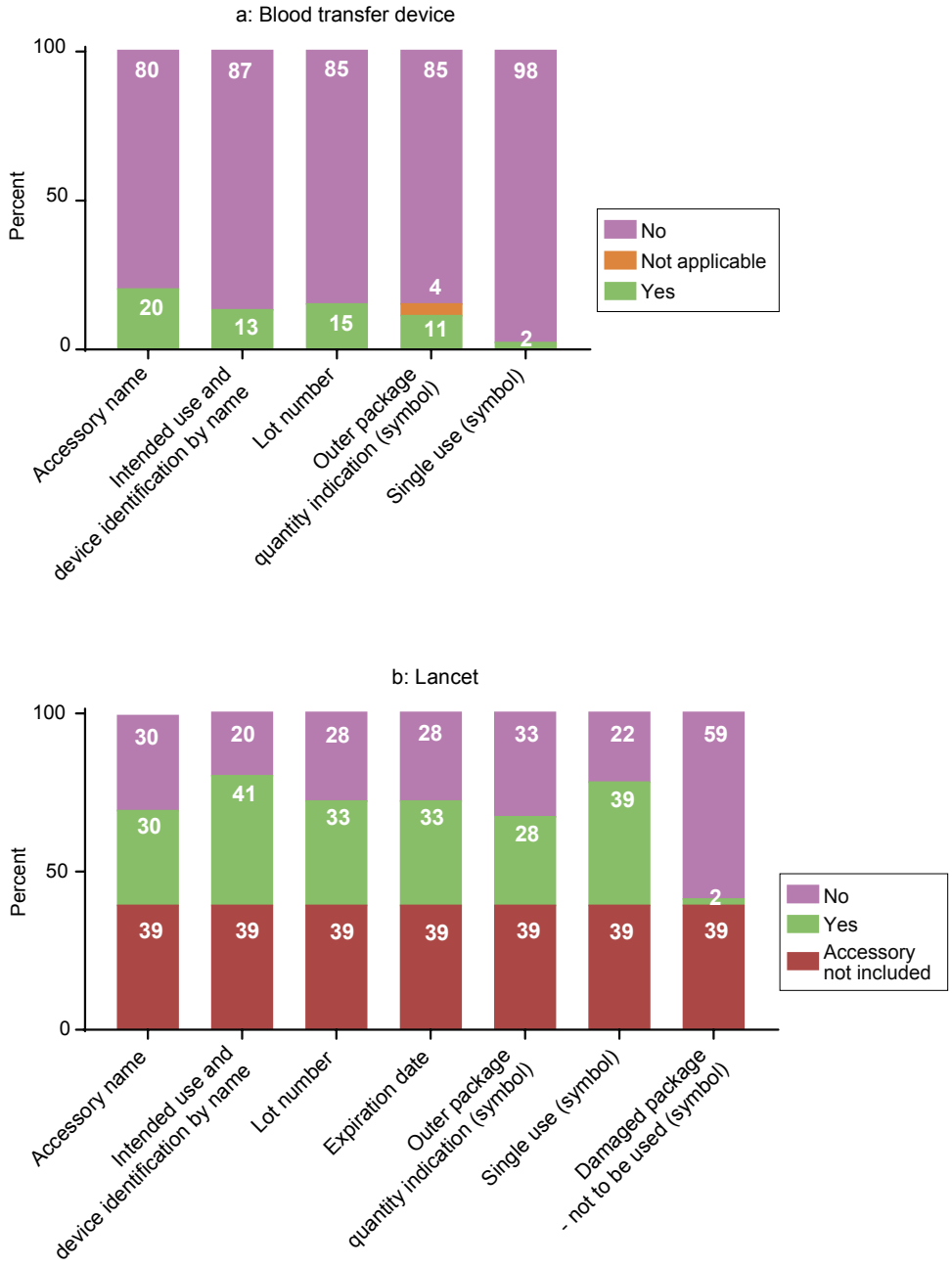


Figure 36: Completeness of information on accessory packaging – dessicant and alcohol swab

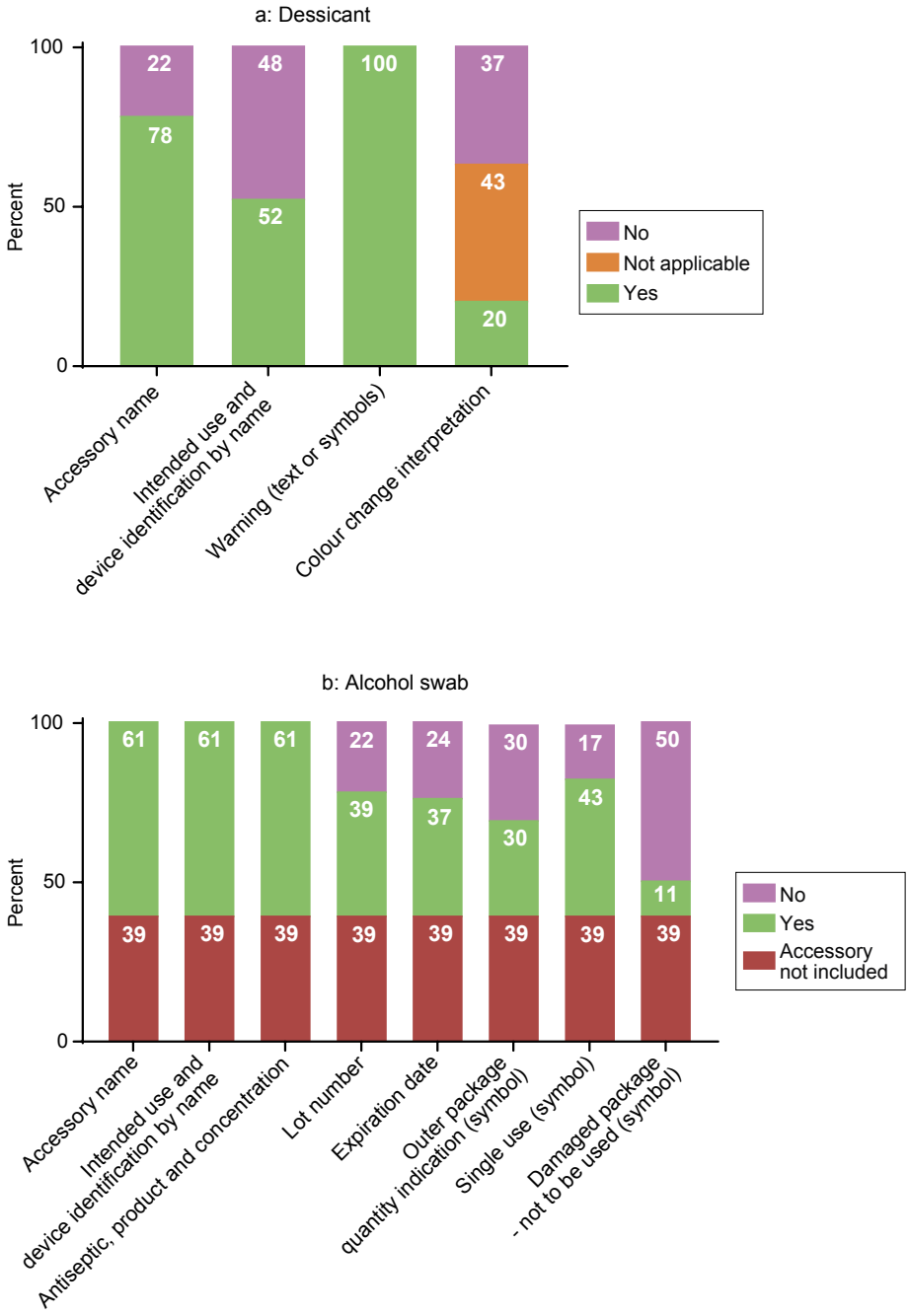


Figure 37: Completeness of information included in the IFU: intended use and precautions and limitations

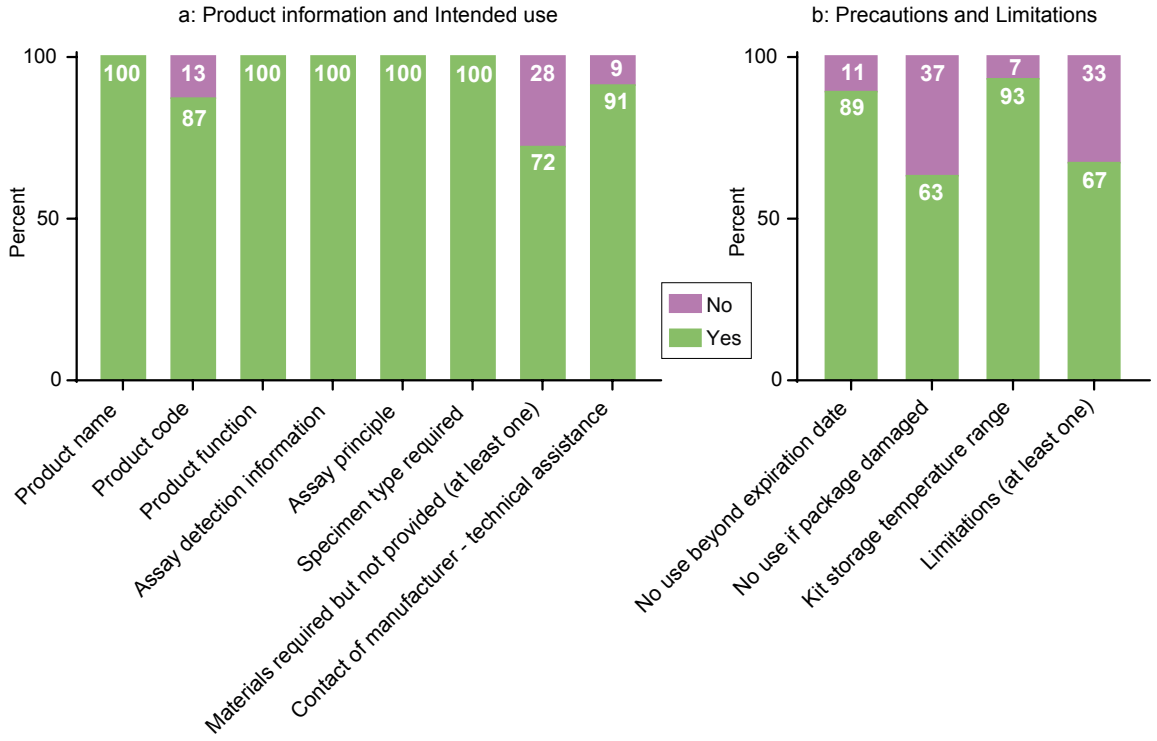


Figure 38: Completeness of information included in the IFU – procedure and performance specifications.

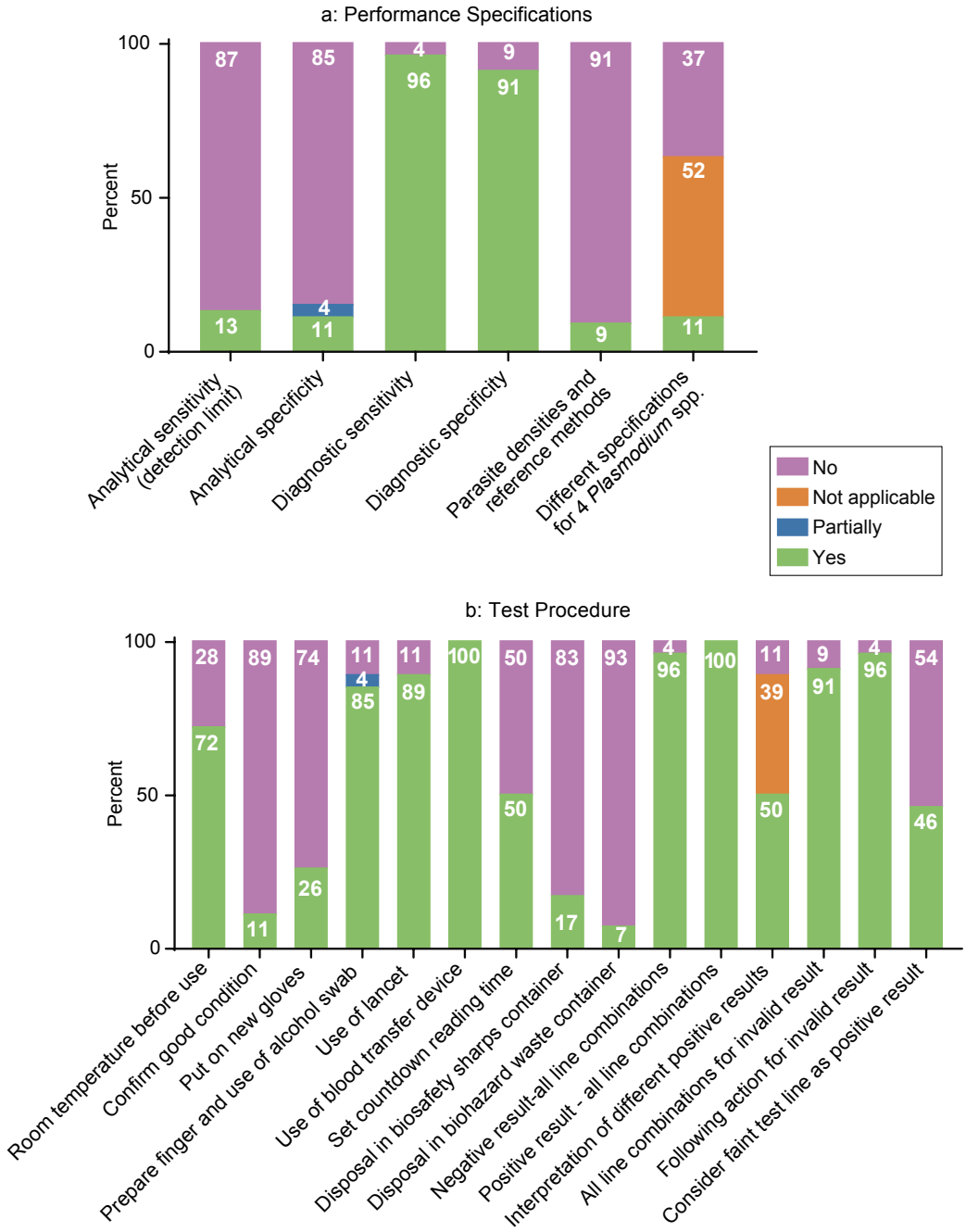


Table 7: Ease-of-use description of 46 malaria RDTs included in round 7

Product	Product code	Manufacturer	Blood safety[a]				Instruction quality[b]				*Combined score* (max. 5)	Number of timed steps	Total time to result	Desiccant with colour 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)	Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)					Container does not puncture	Does not flow freely	Insufficient volume	Empty (bottle or vial)	Discoloured				
Pf only																							
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	1	0	1	2			2	2	4	1	20	no						loop	cassette	English	Alcohol Swab / Lancet
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	1	1	1	3			2	2	5	1	20	no						loop	cassette	English	Alcohol Swab / Lancet
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	1	0	1	2			2	2	4	1	20	yes						loop	cassette	English	Alcohol Swab / Lancet
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English	Alcohol Swab / Lancet
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	Alcohol Swab / Lancet
careUS™ Malaria Pf (HRP2) Ag"	RMO-M05082	WELLS BIO, INC	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	Alcohol Swab / Lancet
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English, German	Alcohol Swab / Lancet
GMD Malaria Pf test	MDMALPFH005	Medical Diagnostech (Pty) Ltd	1	0	1	2			2	2	4	1	30	no						pipette	cassette	English	Alcohol Swab / Lancet
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	1	0	1	2			2	2	4	1	15	yes						inverted cup	cassette	English	Alcohol Swab / Lancet
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	1	1	1	3			2	2	5	1	15	no						inverted cup	cassette	English	Alcohol Swab / Lancet
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1	2			2	2	4	1	15	yes						pipette	cassette	English	Alcohol Swab / Lancet
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	GMDMALPF001	Meril Diagnostics Pvt. Ltd.	1	NA	1	2		1		1	3	1	20	no						pipette	cassette	English	
PALUTOP + pf®	5531	ALLDIAG SA	1	NA	1	2			2	2	4	1	20	no						loop	cassette	English, French	
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	1	1	0	2			2	2	4	1	25	no						pipette	dipstick	English	Alcohol Swab / Lancet
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	1	1	1	3			2	2	5	1	25	no						pipette	cassette	English	Alcohol Swab / Lancet
Alere™ Malaria Ag P.f.	05FK140-40-0	Standard Diagnostics, Inc.	1	0	1	2			2	2	4	1	20	yes						inverted cup	cassette	English	Alcohol Swab / Lancet
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	1	0	1	2			2	2	4	1	15	yes						inverted cup	cassette	English	Alcohol Swab / Lancet
Pf and Pan																							
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English	Alcohol Swab / Lancet
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English	Alcohol Swab / Lancet
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	1	NA	1	2			2	2	4	1	30	no						loop	cassette	English	
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	1	NA	1	2			2	2	4	1	30	no						loop	cassette	English	
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	1	0	1	2			2	2	4	1	20	yes						loop	cassette	English	Alcohol Swab / Lancet
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	1	NA	1	2			2	2	4	1	15	no						inverted cup	cassette	English	

Table 7: Ease-of-use description of 46 malaria RDTs included in round 7 *(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 colour 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)	Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)					Container does not puncture	Does not flow freely	Insufficient volume	Empty (bottle or vial)	Discoloured				
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	1	NA	1	2			2	2	4	1	10	no						pipette	cassette	English	
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	Alcohol Swab / Lancet
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	1	0	1	2			2	2	4	1	30	no						inverted cup	cassette	English	Alcohol Swab / Lancet
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	1	NA	1	2			2	2	4	1	20	yes		x				loop	cassette	English	
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	1	0	1	2			2	2	4	1	30	yes						pipette	cassette	English	
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	1	NA	1	2			2	2	4	1	30	no						pipette	cassette	English	
Pf and Pv																							
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-05072	Access Bio, Inc.	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	Alcohol Swab / Lancet
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	1	0	1	2			2	2	4	1	20	no						inverted cup	cassette	English	Alcohol Swab / Lancet
Rapid Test Kit for Malaria Ag Pf/Pv- Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	1	NA	1	2			2	2	4	1	30	no						loop	cassette	English	
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	1	1	1	3			2	2	5	1	20	no						loop	cassette	English	Alcohol Swab / Lancet
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	1	NA	1	2			2	2	4	1	15	no						inverted cup	cassette	English	
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	1	0	1	2			2	2	4	1	15	yes						pipette	cassette	English	Alcohol Swab / Lancet
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	1	0	1	2			2	2	4	1	20	no						loop	cassette	English	Alcohol Swab / Lancet
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	
Malaria Pf/PAN Test	PROMALPFV001	Real World Diagnostics	1	0	1	2			2	2	4	1	30	no						pipette	cassette	English	Alcohol Swab / Lancet
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	1	NA	1	2		1		1	3	1	20	no						pipette	cassette	English	
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	1	NA	1	2			2	2	4	1	30	no						pipette	cassette	English	
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	1	0	1	2			2	2	4	1	20	no						pipette	cassette	English	Alcohol Swab / Lancet
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	1	NA	1	2			2	2	4	1	20	no						pipette	cassette	English	
Pf and Pv and Pan																							
PALUTOP +4 optima®	5499	ALLDIAG SA	1	NA	1	2			2	2	4	1	20	no						loop	cassette	English, French	

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)	Patchy broken test line
Pf only										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0.1	0.0	0.0	0.0	0.0	0.0	0.1	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.2	0.1	0.0	0.0	0.0	0.0	0.1	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	0.2	0.1	0.0	0.0	0.0	0.0	0.0	0.1
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	1.4	0.8	0.4	0.2	0.0	0.0	0.0	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0.1	0.0	0.0	0.1	0.0	0.0	0.0	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0.2	0.0	0.0	0.1	0.0	0.0	0.1	0.0
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	0.2	0.1	0.1	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0
Pf and Pan										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.2	0.1	0.0	0.1	0.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.1	0.0	0.0	0.0	0.1	0.0	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0.6	0.0	0.0	0.4	0.1	0.2	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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.	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.5	0.2	0.0	0.3	0.0	0.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.1	0.0	0.0	0.0	0.0	0.1	0.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.5	0.5	0.0	0.1	0.0	0.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0.8	0.2	0.0	0.5	0.0	0.2	0.0	0.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0.2	0.2	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.2	0.2	0.0	0.0	0.0	0.0	0.1	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)	Patchy broken test line
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.2	0.0	0.0	0.0	0.2	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.6	0.3	0.1	0.2	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.2	0.2	0.0	0.0	0.1	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.7	0.4	0.1	0.0	0.2	0.1	0.0	0.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0.3	0.0	0.0	0.3	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	1.4	0.6	0.1	0.5	0.1	0.0	0.0	0.1
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.1	0.1	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan										
PALUTOP +4 optima®	5499	ALLDIAG SA	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.1

15. DISCUSSION OF KEY FINDINGS

This report describes the performance of many of the commercially available malaria antigen-detecting RDTs manufactured under the ISO 13485:2003 quality standard. For malaria RDTs to improve the management of febrile illness in malaria-endemic areas, they must have adequate:

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

Malaria RDTs were evaluated in terms of these four requirements in order to assist national malaria control programmes and other procurement agencies in selecting products appropriate for their needs. The evaluation constitutes the laboratory component of the WHO programme for prequalification of in vitro diagnostics. The panel used ensured successful discrimination between the RDTs evaluated. A number of products showed a high rate of antigen detection, a low false-positive rate and good heat stability. These attributes are essential for tests used as a basis for decisions about malaria treatment in the populations of most malaria-endemic countries.

Overall, the mean PDS against low-density *P. falciparum* samples in round 7 was 87.2%, slightly higher than in round 6 (83.6%) and continuing the pattern of improvements in each round.[1] For *P. vivax* tests, the mean PDS of 76.8% is the highest achieved so far.[2] The median false-positive rate was 0%, which is lower than in round 6 (0.5%). 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. As previously, too few Pf-pLDH-based RDTs were submitted for evaluation: only three were assessed in round 7. The mean PDS (at 200 parasites/µL) was 62% (range, 38–75%) in rounds 2–6 (17 products) and 2.0–88.9% in rounds 2–7.

Five products tested in round 3 of the programme were resubmitted for testing in round 7. Two performed better 5 years after initial testing, but three performed less well, and two of these no longer met the WHO criteria for procurement.

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 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 tests had to be positive in order for a sample to be considered "detected" by an RDT, a positive result indicates 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 (*11*).

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**

[1] The PDS values for *P. falciparum* in rounds 1, 2, 3, 4 and 5 were 67.2%, 69.9%, 75.5%, 81.6% and 81.0%, respectively.

[2] The PDS values for *P. vivax* in rounds 1, 2, 3 , 4, 5 and 6 were 36.0%, 58.9%, 47.1%, 51.3%, 61.3% and 70.7%, respectively.

of the intended users, ease of use (Annex S2) and manufacturing capacity, may be equally important in test selection. Consideration of the parasite density in target populations and the probable sensitivity of RDTs in the field indicates that, even in areas with high transmission and strong malaria immunity, the population may include individuals with a low parasite density but clinically significant infection (e.g. young children, pregnant women, people who regularly use bed nets, immigrants and people with reduced immunity). The ability to detect low parasite-density infections reliably, therefore, remains important. As some countries move towards elimination of malaria, population immunity will decrease and/or clinical cases may be detected earlier, and it could 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 Africa (Eritrea *(33)*, Democratic Republic of the Congo), India *(13)* and South America *(34)* do not express HRP2 antigens because of gene deletions (*12–13*). If a significant proportion of parasites in a given area do not express HRP2 and HRP3, leading to false negative results, 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 been identified in several countries in South America *(12)* and in Eritrea *(33, 34)*. The reactivity of the non-HRP2, Pf-specific test lines against phase 1 and 2 Pf (HRP2-containing) samples is currently the best predictor of how well these RDTs would detect *pfhrp2*-negative parasites. In most cases, the Pf panel detection score for products based on pf-pLDH-specific test lines is < 75, the cut-off for procurement. In round 7, one combination test met the procurement criterion, with a PDS of 75 against 200 parasites/µL Pf samples. For a summary of options and test performance in round 7 and previous rounds, refer to the WHO interim guidance on investigating false-negative RDTs and *pfhrp2/3* gene deletions.[1]

(iv) The conditions under which RDTs are transported and stored can alter their sensitivity in the field. The tests evaluated in round 7 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 (*32, 35*).

[1] http://apps.who.int/iris/bitstream/10665/208819/1/WHO_HTM_GMP_2016.4_eng.pdf (accessed 8 March 2017).

(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 (*36*).

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.

15.4. Heat (thermal) stability

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 were highly stable at the temperatures and times used in the evaluation. 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*, many of the pan-pLDH lines were highly stable at all temperatures and times tested. In most products, the *P. vivax* pLDH lines were also highly stable. These results for *P. vivax* are an improvement over round 6.

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 (*37, 38*).

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 (*39*). 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 (*31*). 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. Although the intensity of the test band was found to be correlated with the PDS of RDTs, PDS is determined only from a positive or negative result under ideal working conditions. Thus, it is important when selecting RDTs also to consider the relative intensity of the test bands, with a preference for intense bands (i.e. an intensity > 2).

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 (*40, 41*). Annex S2 provides guidance on conducting a field-based ease-of-use assessment (Table AS3.1).

15.6. Labelling and instructions for use

The labelling on primary packaging (the box), device packaging and the device itself was generally consistent and adhered to most of the recommendations. A notable exception was that almost all products failed to include warning labels on the boxes and cassette packaging. Much poorer adherence to the recommendations and less consistency among products was seen in labelling of buffers and other accessories.

Adherence to the recommendations for instructions for use was variable. Product information and intended use were generally included, with notable exceptions, such as the failure to list all the materials required but not provided. Other aspects of the instructions often did not meet the recommendations; for example, the instructions for over one third of the products did not include precautionary notes on the use of damaged products or product limitations. With regard to performance, the instructions for most products covered diagnostic sensitivity and specificity, but very few included analytical sensitivity and specificity or issues of parasite density and reference methods. Adherence to the recommendations for information on procedures was generally poor, particularly for safety practices and interpretation: fewer than half the product instructions advised that a faint line should be considered a positive result.

Wide differences in how information is presented to users can affect the ease and consistency of use and potentially affect proper use. There is considerable scope for improvement in the instructions for use of currently recommended products.

15.7. Anomalies in RDT production lots

Anomalies that affected interpretation of the results were encountered with variable frequency in the production lots submitted for evaluation. A glossary of RDT anomalies has been prepared (Fig. AS2.1) on the basis of the experience of several rounds of product testing, with 4095 lots tested in the WHO–FIND lot testing programme. 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.

15.8. Inter-lot variation

Only two production lots of each product were evaluated in the testing programme. 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]

15.9. Selecting RDTs: target antigens, species and sensitivity

Target antigens

The malaria RDTs evaluated 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.

In choosing an RDT, account should be taken of the target antigen: HRP2-detecting RDTs should not be used in areas where false negative RDT rates due to non-expression of HRP2 is common (> 5%) (*33, 34*). Five *P. falciparum* RDT products were evaluated in round 7 that detected *P. falciparum* with Pf-pLDH, two combination tests had only Pf-pLDH, and three had HRP2 as well. Of the three with both HRP2 and Pf-pLDH, two combined the two antigens on a single test line, and the other had two separate test lines to detect *P. falciparum*. Only one of the three products with separate pf-pLDH test lines met WHO procurement criteria with a *P. falciparum* PDS of 75% at 200p/µl. However, the pf-pLDH test lines on all three products performed well at 2000p/µl (PDS range: 92-100%). Detection of Pf-pLDH is known to be less sensitive than detection of HRP2 at low parasite densities, and low-density infections with HRP2-deleted *P. falciparum* parasites could therefore 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.

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

Species-specific vs non-species-specific RDTs

RDTs are mainly tools for making clinical decisions, but their role in surveillance has grown dramatically. If all infections are managed in the same way, ie. with artemisinin-based combination therapy, there is no clinical advantage of having an RDT that can distinguish falciparum from non-falciparum infection: a pan-only test would suffice. If treatment of the two infections is different, however, distinguishing between falciparum and non-falciparum infection is a priority, and a combination test must be used (Pf/Pan). When the results of RDTs are used for species-specific monitoring, a species-specific RDT is preferable (Pf/Pv). No currently available RDT can specifically identify *P. malariae* or *P. ovale* infections. Furthermore, pan-species and Pvom tests are not evaluated against these, as there is no source of suitable mono-species infections. Published data suggest, however, that the sensitivity of RDTs for detecting these species is significantly poorer than that for detecting *P. falciparum* and *P. vivax* (*42*).

RDT sensitivity and the role of highly sensitive diagnostic tools

RDTs are considered to be tools to detect symptomatic malaria infections, with ≥ 200 parasites/µL (*11*); however, the threshold of parasitaemia associated with symptoms depends on both transmission intensity and individual immunity to malaria. In a review of parasite densities in various epidemiological settings *(43)*, the best estimate of the proportion of symptomatic people with a parasite density >200 parasites/µL who seek care at a health facility was 90-95% for *P. falciparum* and approximately 85% (range, 78-92%) for *P. vivax*. The performance panels used in product testing challenge the RDTs to consistently detect samples with antigen concentrations at the 200 parasites/µL threshold, corresponding to minimal HRP2 antigen concentrations of 0.59-0.80ng/mL and expected to detect the majority of clinically symptomatic malaria infections in endemic settings. The individual and public health benefits of detecting and treating submicroscopic or very-low-density parasitaemia are poorly understood and would require rigorous risk-benefit analysis *(44,45)*. Nonetheless, highly sensitive tests like PCR and LAMP have been used for surveillance and focus investigation in low-transmission areas, and a highly sensitive HRP2-based RDT (Alere™ Malaria Ag Pf (05FK140), Standard Diagnostics) has been commercialized with claims of an analytical sensitivity of 0.05–0.08 ng/mL of HRP2 *(46)*. This is approximately 10 times the detection limit of the best conventional RDTs that detect the samples in the product testing panel. (Annex S1). The current performance panels cannot discriminate between products that can detect samples with antigen concentrations comparable to < 200 parasites/µL (considered to be highly sensitive) and those that detect only > 200 parasites/µL (conventional RDTs). Therefore, as expected, the performance of the highly sensitive RDT in round 7 was similar to that of other high-performing conventional RDT able to detect the majority of clinically significant infections. As for other high sensitive tests, the use of the high-sensitive HRP2-based RDT evaluated in round 7 is not recommended for malaria clinical case management, as it is anticipated to lead to the problems listed below:

I) Detection of low levels of HRP2 antigen concentrations associated with low density falciparum infections may be associated with decreased specificity of diagnosis of clinical malaria. Since the association between antigenemia and parasitemia and fever varies from place to place, season to season, their use may potentially lead to misdiagnosis and overtreatment of fever, as malaria.

ii) Persistent HRP2 antigenemia over longer period following successful treatment may also cause more false positive clinical cases.

iii) If highly sensitive diagnostic tests are used for clinical case management or surveys, there is a potential threat of antimalarial stock outs due to increased test positivity caused by low density, asymptomatic infections.

iv) If end-users abruptly see an unexpected increase in the number of malaria cases following the introduction of a highly sensitive RDT, this may undermine their confidence in conventional malaria RDTs as case management tools for acute febrile illness.

More research is needed to determine the clinical consequences of submicroscopic infections, their contribution to onward disease transmission and the role of highly sensitive diagnostic tests in surveillance for targeting malaria elimination.

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. The report does not provide a list for procurement but should aid potential buyers by providing comparative data on the performance of the available products. Final product selection requires that these data be considered systematically, taking into account the distribution of parasite density in the target population in whom the tests will be used, the experience and training of the intended users and other criteria such as climate and transport/storage conditions, price and supply aspects, and others. Box 3 lists WHO's *current* 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. As WHO prequalification will become a requirement as of 1 January 2018, the prequalification status of each product is also indicated. 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 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 *Recommended selection criteria for procurement of malaria rapid diagnostic tests*, *Good practices for selecting and procuring rapid diagnostic tests for malaria (16)* and *Universal access to malaria diagnostic testing (17)*.

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 *(46)*.

[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: https://www.finddx.org/malaria/interactive-guide/ (accessed 8 March 2017).

16.1. WHO prequalification

The WHO programme for prequalification of in vitro diagnostics 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, assessment of technical documentation (dossier review) and an independent performance evaluation.

The results of the WHO malaria product testing programme fulfill the performance evaluation component of the prequalification process. Twelve malaria RDT products have been prequalified.[2] Prequalification has not been a requirement for eligibility for United Nations procurement tenders for malaria RDTs, as it is for other RDTs, such as for HIV; however, WHO prequalification will determine the eligibility of malaria RDTs for procurement after 31 December 2017. WHO product testing will continue to be the independent performance laboratory evaluation component of the prequalification process. Round 8 of product testing is under way All manufacturers who submit products to round 8 are required also to submit applications for WHO prequalification.

16.2. Beyond procurement

Diagnostic tests are usually used at 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.

While this report does not provide a list for procurement, it 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 (*17*).

[2] http://www.who.int/diagnostics_laboratory/evaluations/pq-list/malaria/public_report/en/ (accessed 8 March 2017).

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 shipment from the production facility 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, and, more recently, several countries have begun pilot-testing malaria recombinant antigen panels to monitor trends in lot performance. 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 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 6 months before expiry. Initial results are available after 5 days, and definitive results after subsequent confirmatory tesing, if required. Details of the protocol can be found in the methods manual for lot testing (*27*). 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, or even defects of some kit accessories, 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 *christian.nsanzabana@finddx.org* and cc: *Malaria_rdt@who.int* 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 regularly since 2009 (*3–8*). 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, its independence 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. Round 7 introduced a new component of the product evaluation: examining the labelling and instructions for use associated with each product in a standardized manner, to demonstrate their performance against a set of standards for these components. 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, 48*). The report of round 7 adds to the number of well-performing RDTs for which comprehensive performance data are now available including the first high-sensitive RDT and provides updated data on 15 product resubmissions.

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ANNEXES

Annex S1: Characteristics of evaluation panels used in rounds 1–7 of WHO malaria RDT product testing, 2008–2016

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.

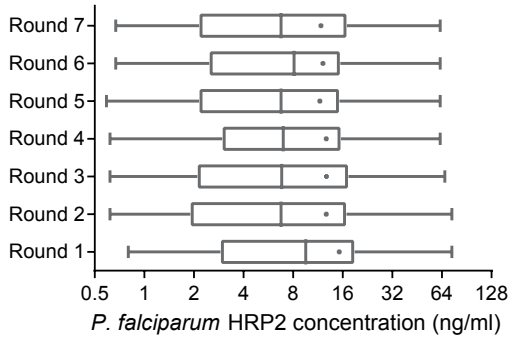


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

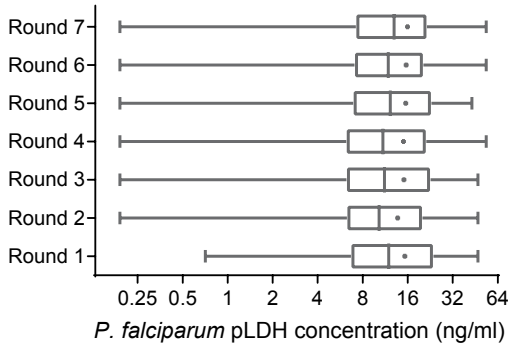


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

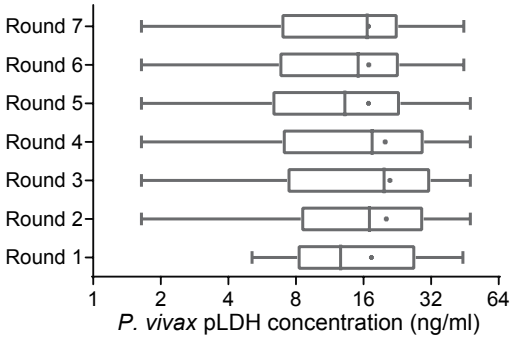


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

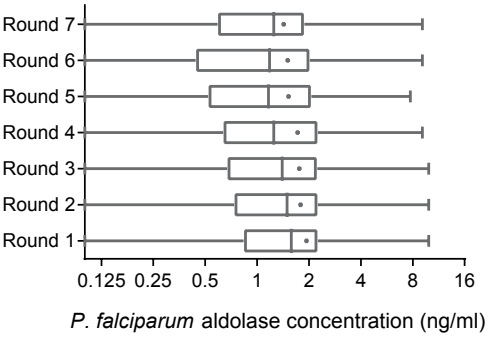


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

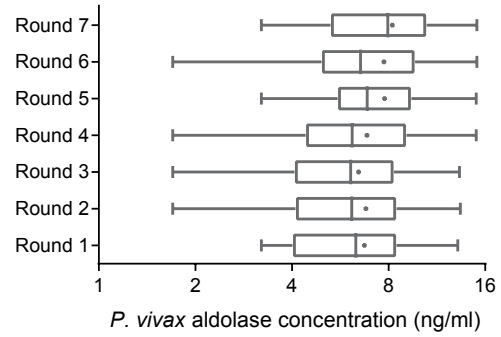


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Number of values[a]	78	99	99	98	99	99	99
Minimum	0.80	0.62	0.62	0.62	0.59	0.67	0.67
25% percentile	2.90	1.90	2.10	2.97	2.15	2.48	2.15
Median	9.57	6.76	6.83	6.98	6.76	8.12	6.76
75% percentile	18.94	16.91	17.37	15.65	15.31	15.51	16.99
Maximum	73.70	73.70	66.70	62.48	62.48	62.48	62.48
Mean	15.28	12.70	12.77	12.72	11.65	12.15	11.83
Std. Deviation	16.98	15.75	15.19	14.72	13.25	13.29	13.01

[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	Round 7
Number of values[a]	74	93	92	92	94	98	98
Minimum	0.71	0.19	0.19	0.19	0.19	0.19	0.19
25% percentile	6.68	6.27	6.23	6.20	6.90	7.04	7.20
Median	11.95	10.31	11.18	10.92	12.24	11.85	12.99
75% percentile	23.75	20.10	22.70	21.28	23.05	20.36	21.51
Maximum	47.15	47.15	47.15	53.53	43.02	53.53	53.53
Mean	15.31	13.71	15.08	14.97	15.53	15.61	15.93
Std. Deviation	11.47	10.90	11.72	11.98	11.43	12.00	11.60

[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	Round 7
Number of values[a]	20	37	33	32	34	34	35
Minimum	5.10	1.64	1.64	1.64	1.64	1.64	1.64
25% percentile	8.10	8.40	7.30	6.96	6.26	6.72	6.86
Median	12.65	17.00	19.78	17.50	13.22	15.17	16.62
75% percentile	27.40	29.69	31.89	29.84	23.42	23.14	22.89
Maximum	44.40	47.90	47.90	47.90	47.90	44.79	44.79
Mean	17.38	20.24	20.99	20.00	16.84	16.90	16.87
Std. Deviation	11.57	13.27	13.55	13.00	12.59	11.78	11.17

[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	Round 7
Number of values[a]	77	98	99	97	98	99	99
Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00
25% percentile	0.84	0.74	0.67	0.64	0.52	0.44	0.59
Median	1.58	1.49	1.40	1.25	1.17	1.18	1.25
75% percentile	2.25	2.25	2.23	2.25	2.07	2.02	1.88
Maximum	9.90	9.90	9.90	9.08	7.74	9.08	9.08
Mean	1.93	1.79	1.76	1.72	1.52	1.50	1.43
Std. Deviation	1.73	1.66	1.69	1.68	1.52	1.61	1.34

[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	Round 7
Number of values[a]	20	40	34	33	35	35	35
Minimum	3.21	1.70	1.70	1.70	3.21	1.70	3.21
25% percentile	4.02	4.11	4.07	4.41	5.55	4.94	5.27
Median	6.33	6.15	6.10	6.16	6.86	6.54	7.96
75% percentile	8.47	8.47	8.32	9.10	9.43	9.68	10.52
Maximum	13.15	13.40	13.30	15.00	15.00	15.08	15.08
Mean	6.73	6.81	6.45	6.86	7.78	7.74	8.22
Std. Deviation	2.89	3.15	2.90	3.23	3.30	3.69	3.61

[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

Fig. AS2.1 shows examples of observations and anomalies encountered and routinely recorded for RDTs in round 7 of WHO Malaria RDT Product Testing at the CDC. Most of these anomalies would not invalidate the results, as reactivity in the control and test line areas is still visible, but they may pose challenges to health workers in interpreting the results. Furthermore, they should be reported to manufacturers.

An extended list of notable observations on RDT packaging, kit accessories (buffer vials, desiccants) and instructions for use is being prepared for use in both product testing and lot testing in the WHO-FIND Malaria RDT Evaluation Programme.

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

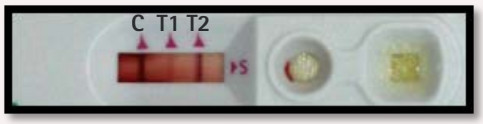
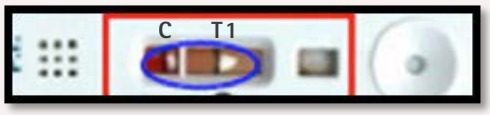
Date of assessment				
Commercial name				
Product code				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed package				
The correctly indicated number of RDTs are in the box				
Desiccant is included 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)				

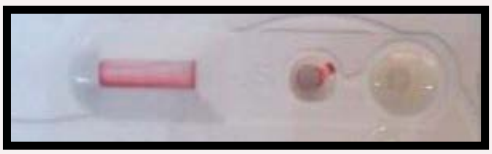
NA, not applicable

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

Step 1.1
Define setting of use

What? target parasite species and antigen[a]

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

****Pf without HRP2 – Do not use exclusively HRP2-based RDTs[c]**

Where?	Exposure to high temperature e.g. tropical environment OR temperature-controlled environment, including during transport and storage
Who?	Laboratory personnel OR health workers outside laboratories

↓

Step 1.2
Review RDT performance

WHO RDT product testing results[d] and apply WHO recommended RDT selection criteria[e]
- Panel detection score
- False-positivity rate
- Invalid rate
- Ease-of-use
- Thermal stability

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

Generate short-list of RDTs

Step 1.3
Apply national guidelines and experience in use of RDTs

National malaria treatment guidelines

↓

In-country experience, ease-of-use assessments (Annex S2), availability of training materials

Step 1.4
Other considerations

- Price
- Manufacturer: production capacity, lead times, heat stability data and storage conditions
- Delivery schedules (e.g. staggered deliveries), box size, shelf life
- Registration requirements of national regulatory authorities
- Product lot testing results
- Overall budget requirements (Annex 5)

[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, Africa (Eritrea, Democratic Republic of the Congo, Ghana) and India (*1–6*).

[d] See references *(7–12)*.

[e] WHO RDT procurement criteria *(13)* : http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/ (accessed 14 June 2017).

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 in the full report *(16)*.

Annex 1: Characteristics of RDTs evaluated in round 7

Manufacturer	Product name	Product code	Sequence and type of bound antibody[b] C	T1	T2	T3	Required volume of whole blood (µl)	Buffer drops	Minimum time to results[c] (mins)	Maximum reading time (mins)	Protocol group[f]	Results Interpretation[d] (type A-J)	Format type[e]	Recommended storage temperature (°Celcius)	Shelf-life (months)
Access Bio, Inc.	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo	RMVM-05072		Pv pLDH	HRP2		5	2	20		1	E	Cassette	1-40	24
Access Bio, Inc.	CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071		Pf pLDH	HRP2		5	2	20		1	J	Cassette	1-40	24
Access Bio, Inc.	CareStart™ Malaria Screen	RMAM-05071		Pan pLDH	HRP2 + Pf pLDH		5	2	20		1	C	Cassette	1-40	24
Access Bio, Inc.	CareStart™ Pf/PAN (pLDH) Ag RDT	RMLM-05071		Pan pLDH	Pf pLDH		5	2	20		1	C	Cassette	4-30	24
Access Bio Ethiopia	CareStart™ Malaria HRP2 (Pf)	RMOM-03091		HRP2			5	2	20		1	A	Cassette	1-40	36
Access Bio Ethiopia	CareStart™ Malaria HRP2/pLDH (Pf/Pv) Combo	RMVM-03091		Pv pLDH	HRP2		5	2	20		1	E	Cassette	1-40	36
Advy Chemical Private Limited	Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016		Pan pLDH	HRP2		5	4	20	30	3	C	Cassette	2-40	24
Advy Chemical Private Limited	Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017		HRP2			5	4	20	30	3	A	Cassette	2-40	24
Alere Medical Private Limited	Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40		Pan pLDH	HRP2		5	4	30	30	5	C	Cassette	1-40	24
Alere Medical Private Limited	SD Bioline Malaria Ag Pf/Pv	05FK80I-40		Pv pLDH	HRP2		5	4	30	30	5	E	Cassette	1-40	24
ALLDIAG SA	PALUTOP +4 optima®	5499		Pan pLDH	Pv pLDH	HRP2	5	2	20	30	1	G	Cassette	4-30	24
ALLDIAG SA	PALUTOP + pf®	5531		HRP2			5	2	20	30	1	A	Cassette	4-45	24
ARKRAY Healthcare Pvt Ltd	Parahit® f Ver 1.0 - Device	55IC104-50		HRP2			8	4	25	30	9	A	Cassette	4-40	24
ARKRAY Healthcare Pvt Ltd	Parahit f® Ver 1.0 - Dipstick	55IC103-50		HRP2			8	4	25	30	9	A	Dipstick	4-40	24
ASAN Pharmaceutical Co., Ltd	Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K		Pan pLDH	HRP2		5	4	30	30	5	C	Cassette	1-30	24
Aspen Laboratories Pvt. Ltd.	Aspen® Malaria Ag Pf/Pv	AS0060		Pan pLDH	HRP2		5	3	20	30	2	C	Cassette	2-40	24
Aspen Laboratories Pvt. Ltd.	Aspen® Malaria Ag Pf	AS0015		HRP2			5	3	20	30	2	A	Cassette	2-40	24
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f Rapid Card	17912		HPR2			5	4	20	20	3	A	Cassette	1-40	24
Bio Focus Co., Ltd.	BioTracer™ Malaria P.f/PAN Rapid Card	17012		Pan pLDH	HPR2		5	4	20	20	3	C	Cassette	1-40	24
Biosynex	Biosynex® Malaria Pf/Pv	0581_K25		Pv pLDH	HRP2		5	4	15	30	7	E	Cassette	2-30	24
Biosynex	Biosynex® Malaria Pf/Pan	0584_K25		Pan pLDH	HRP2		5	4	15	30	7	C	Cassette	2-30	24
DIALAB	DIAQUICK Malaria P.f. Cassette	W06200		HRP2			5	4	20	30	3	A	Cassette	2-30	24
Guangzhou Wondfo Biotech Co., Ltd.	One Step Malaria HRP2 (P.f) Test	W37-C		HRP2			5	4	15	30	7	A	Cassette	1-35	24
Guangzhou Wondfo Biotech Co., Ltd.	One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C		Pv pLDH	HRP2		5	4	15	30	7	E	Cassette	1-35	24
Hangzhou AllTest Biotech Co. Ltd.	AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402		Aldolase	HRP2		5	3	10	20	10	C	Cassette	2-30	24
Hema Diagnostic Systems	Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25		HRP2	Pan pLDH		5	3	20	30	2	D	Cassette	4-30	24
ICT INTERNATIONAL	ICT MALARIA DUAL TEST	ML03		HRP2	Pan pLDH		5	5	30	30	11	D	Cassette	4-40	24
ICT INTERNATIONAL	ICT MALARIA P.F. CASSETTE TEST	ML01		HRP2			5	5	15		12	A	Cassette	4-40	24
InTec Products, Inc.	ADVANCED QUALITY ™ ONE STEP Malaria (p.f) Test	ITP11002-TC25		HRP2			5	3	20		2	A	Cassette	2-40	24
InTec Products, Inc.	ADVANCED QUALITY ™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25		Pv pLDH	HRP2		5	3	20		2	E	Cassette	2-40	24
Lumiquick Diagnostics Inc.	QuickProfile™ Malaria Pf/Pv Antigen Test	71050		Pv pLDH	HRP2		5	3	20		2	E	Cassette	4-30	18
Medical Diagnostech (Pty) Ltd	MD Malaria Pf	MDMALPFH005		HRP2			5	4	30		5	A	Cassette	4-40	24
Medical Diagnostech (Pty) Ltd	MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004		HRP2	Pv pLDH		5	4	30		5	F	Cassette	4-40	24

(continued)

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

Manufacturer	Product name	Product code	Sequence and type of bound antibody[b] C	T1	T2	T3	Required volume of whole blood (µl)	Buffer drops	Minimum time to results[c] (mins)	Maximum reading time (mins)	Protocol group[f]	Results Interpretation[d] (type A-J)	Format type[e]	Recommended storage temperature (°Celcius)	Shelf-life (months)
Medsource Ozone Biomedicals Pvt. Ltd.	Is It... Malaria Pf PAN	MPFPAN050		Pan pLDH	HRP2		5	3	20	25	2	C	Cassette	2-40	24
Meril Diagnostics Pvt. Ltd.	One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02		Pv pLDH	HRP2		5	4	20	30	3	E	Cassette	2-30	18
Meril Diagnostics Pvt. Ltd.	One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01		HRP2			5	4	20	30	3	A	Cassette	2-30	18
NG Biotech	NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL- W23-005		HRP2	Pan pLDH		5	4	30	30	5	D	Cassette	2-40	24
RapiGEN Inc.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25		Pan pLDH	HRP2		5	4	30	30	5	C	Cassette	1-40	24
RapiGEN Inc.	BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25		Pv pLDH	Pf pLDH		5	4	30	30	5	E	Cassette	1-40	24
Shanghai Kehua Bio-engineering Co., Ltd.	KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C		HRP2			5	4	15	20	7	A	Cassette	4-30	24
Standard Diagnostics, Inc.	SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0		HRP2 + Pf pLDH			5	4	15		7	A	Cassette	1-40	24
Standard Diagnostics, Inc.	Alere™ Malaria Ag P.f	05FK140-40-0		HRP2			5	4	20		3	A	Cassette	1-30	12
WELLS BIO, INC	careUS™ Malaria Pf (HRP2) Ag	RMO-M05082		HRP2			5	2	20		1	A	Cassette	1-40	42
WELLS BIO, INC	careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082		Pv pLDH	HRP2		5	2	20		1	E	Cassette	1-40	24
Zhejiang Orient Gene Biotech Co., Ltd.	Malaria Pf Rapid Test	GCMAL(pf)-402a		HRP2			5	3	20	30	2	A	Cassette	2-30	24
Zhejiang Orient Gene Biotech Co., Ltd.	Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a		HRP2	Pv pLDH		5	3	20	30	2	F	Cassette	2-30	24

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

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

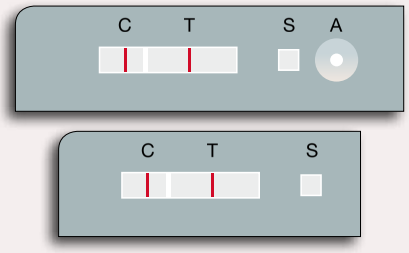
[c] From placement of buffer, or from 'intermediate' step, if applicable

[d] See Annex 2

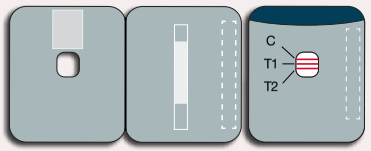
[e] Formats include: cassette (A); card (B); hybrid (C), dipstick (D); or other (E). Each product should ideally be accompanied by all required materials (lancet, pipette, etc.) particularly when used at the village health worker level; however, this is often not the case and the contents depend on the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

[f] 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; group 9: 8µL, 4 drops, 25 mins; group 10: 5µL, 3 drops, 10 mins ; group 11: 5µL, 5 drops, 30 mins; group 12: 5µL, 5 drops, 15 mins.

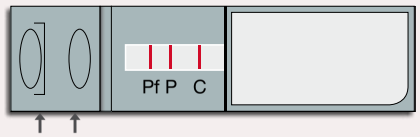
A Cassette



B Card



C Cassette hybrid



Sample and mixing wells

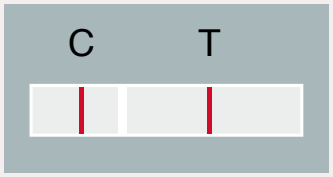
D Dipstick

E Other

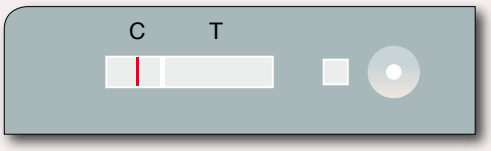
Annex 2: Malaria RDTs: guide to interpretation of results

Type A: Guide to results of generic Pf malaria RDTs

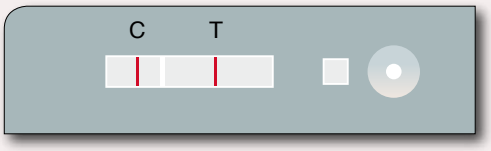
Results window: C=control line; T=test line with bound HRP2 or Pf-specific pLDH antibody.



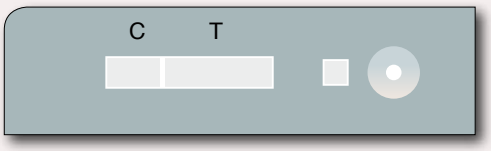
Negative results: One line 'C' appears in the results window.

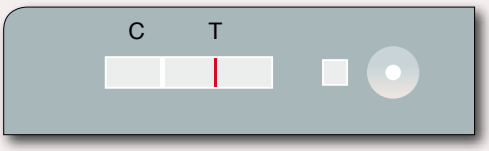


Positive results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window.
Test is positive even if the test line is faint.



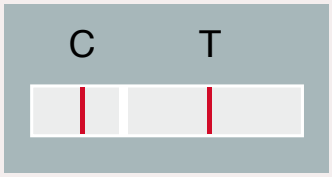
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



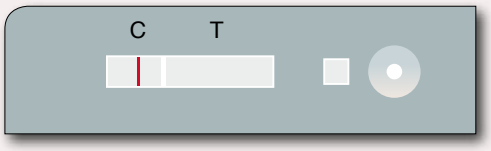


Type B: Guide to results of generic major *Plasmodium* species (pan) malaria RDTs

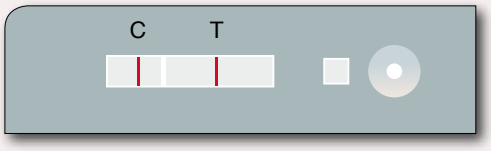
Results window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



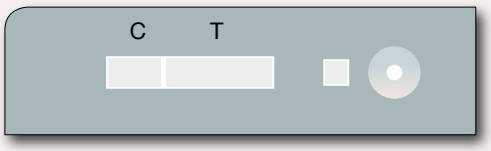
Negative results: One line 'C' appears in the results window.

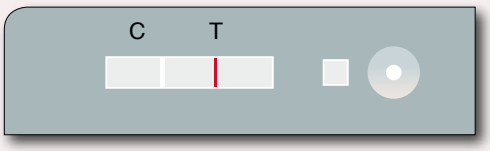


Positive results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



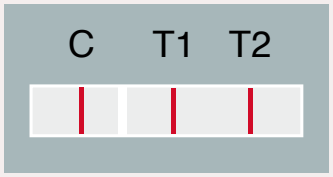
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



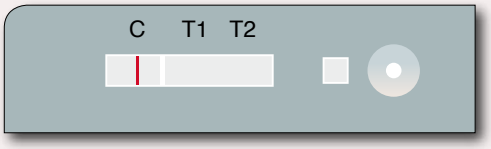


Type C: Guide to results of generic pan-Pf malaria RDTs

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.

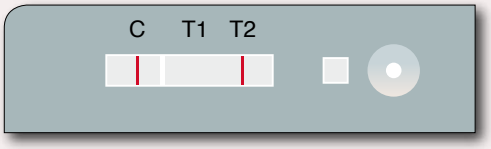


Negative results: Only one line 'C' appears in the results window.

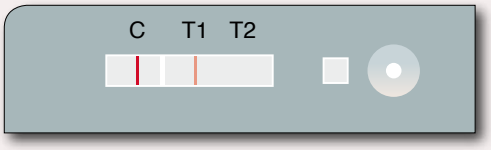


Positive results:

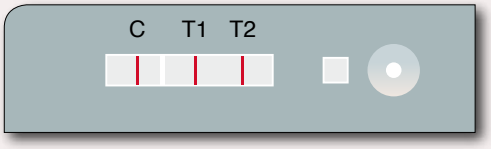
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



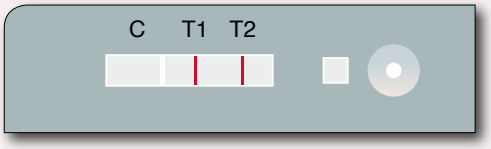
Non-*falciparum* infection (*P. vivax, P. ovale, P. malariae*) or mixed infection:
Two lines 'C' and 'T1" appear in the results window.

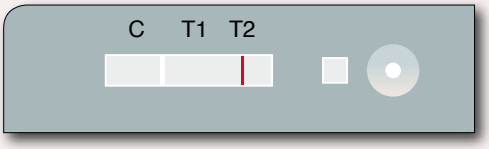


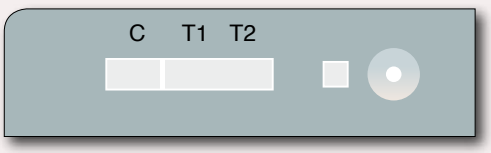
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

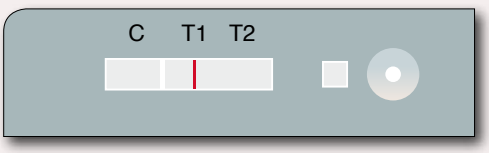


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



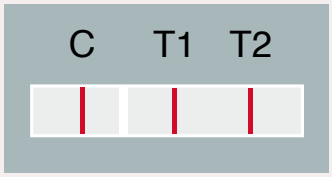




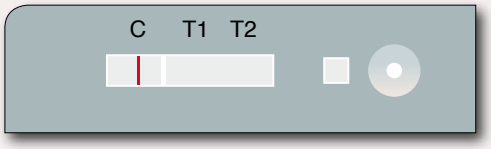


Type D: Guide to results of generic Pf-pan malaria RDTs

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.

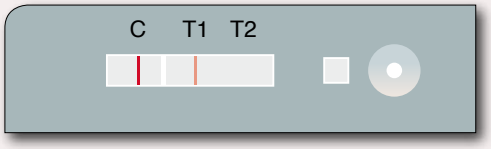


Negative results: Only one line 'C' appears in the results window.

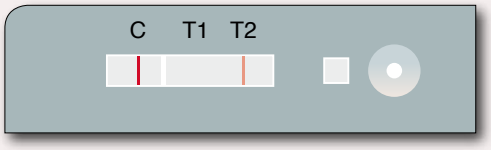


Positive results:

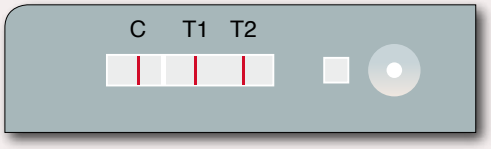
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



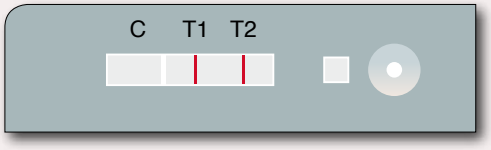
Non-*falciparum* infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection.
Two lines 'C' and 'T2' appear in the results window.

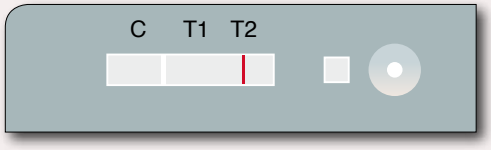


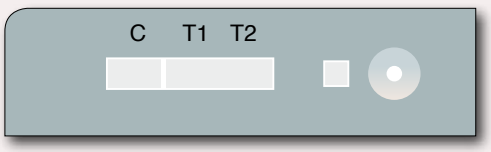
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

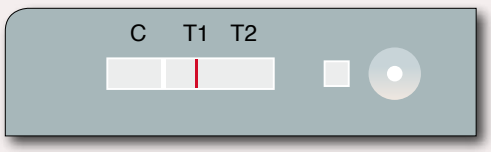


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



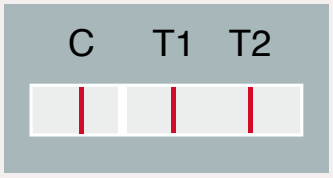




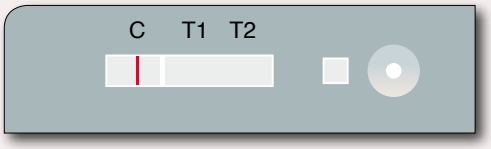


Type E: Guide to results of generic Pv-Pf malaria RDTs

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.

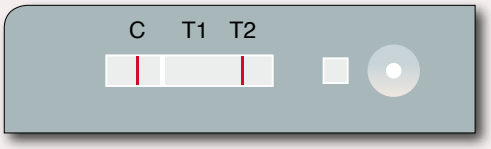


Negative results: Only one line 'C' appears in the results window.

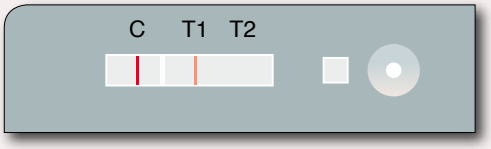


Positive results:

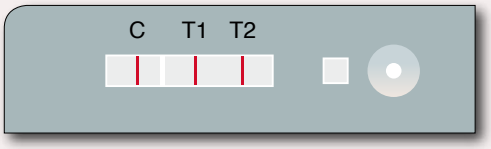
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



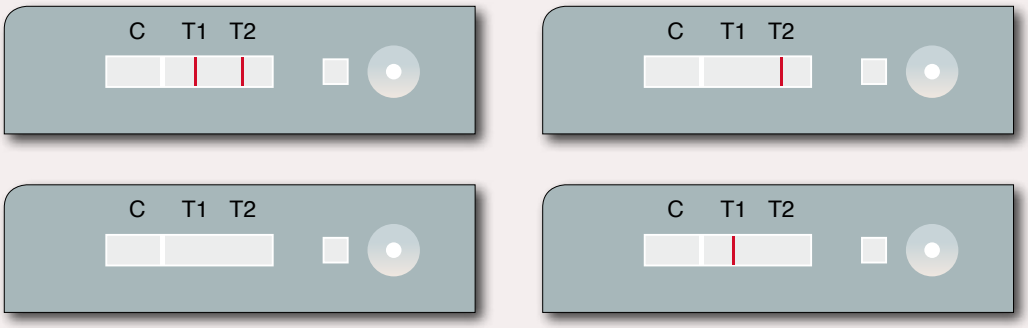
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



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

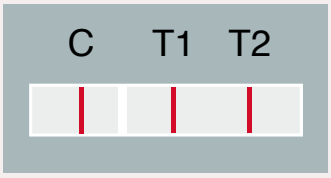


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

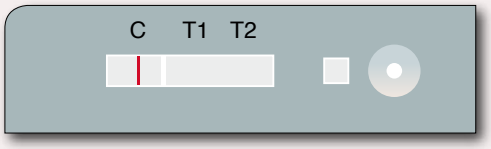


Type F: Guide to results of generic Pf-Pv malaria RDTs

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.

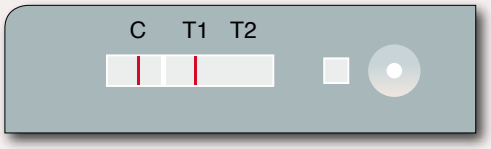


Negative results: Only one line 'C' appears in the results window.

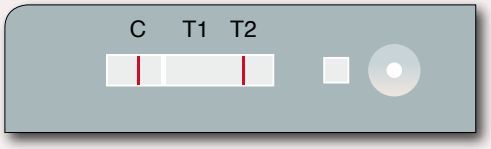


Positive results:

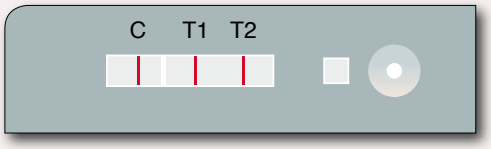
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



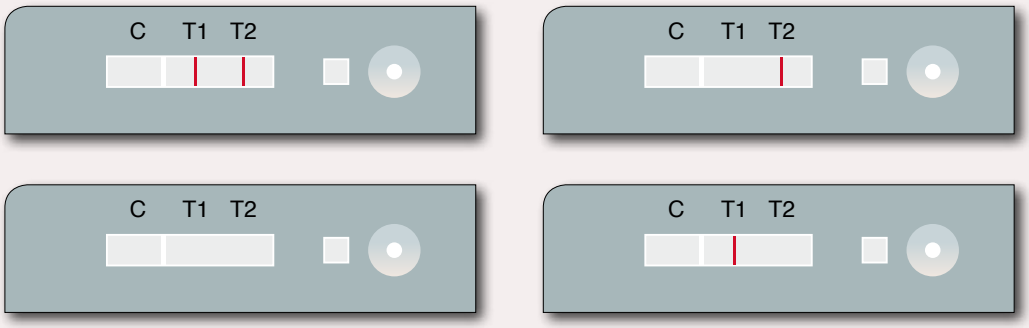
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



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

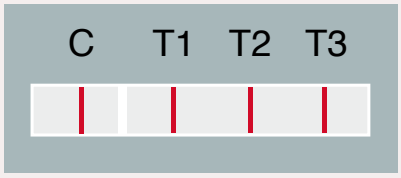


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

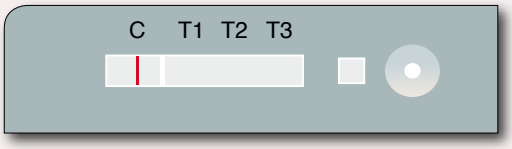


Type G: Guide to results of generic pan-Pv-Pf malaria RDTs

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

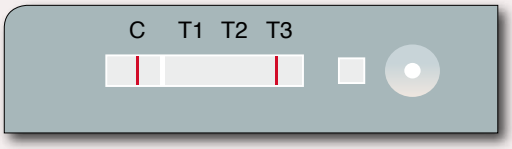


Negative results: Only one line 'C' appears in the results window.

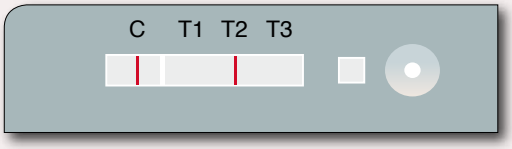


Positive results:

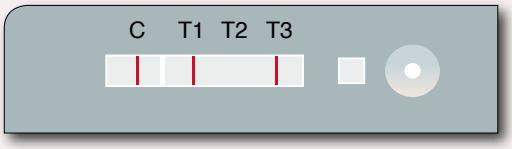
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



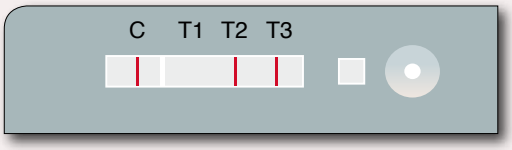
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



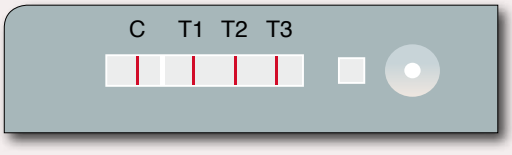
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



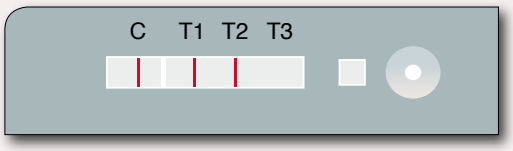
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



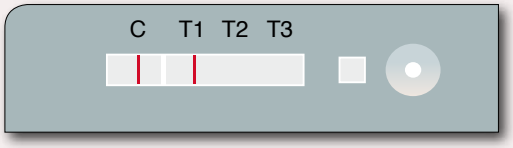
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



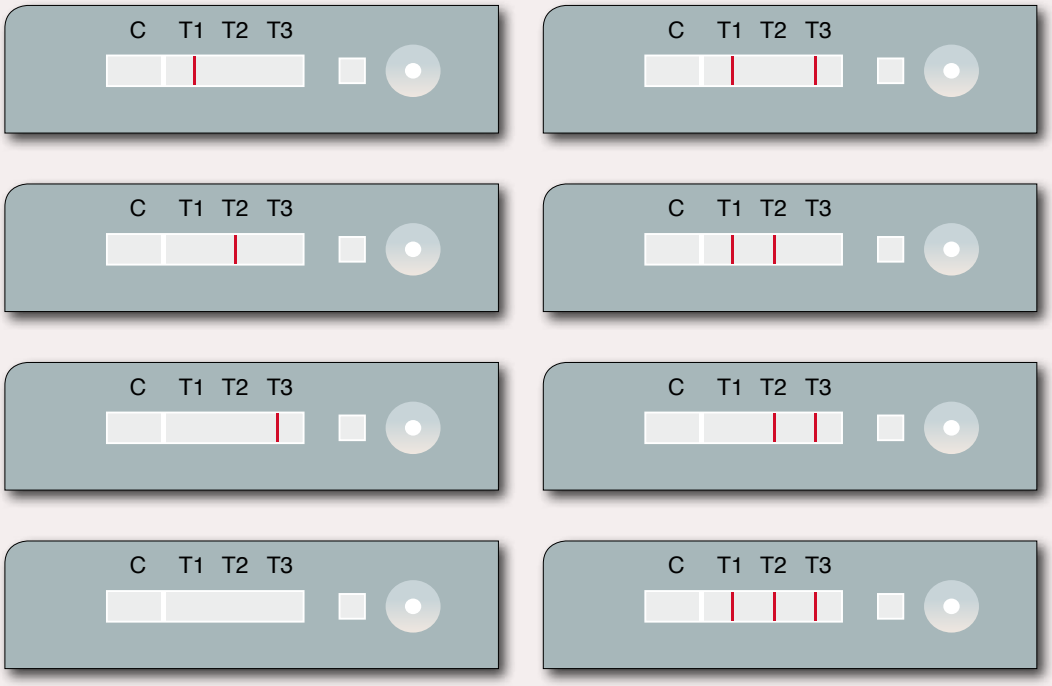
P. vivax **with or without** *P. ovale* **and/or** *P. malariae* **infection. Three lines 'C', 'T1' and 'T2' appear in the results window.**



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

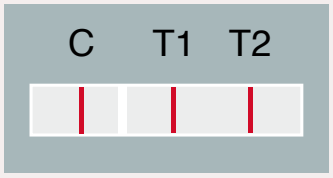


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

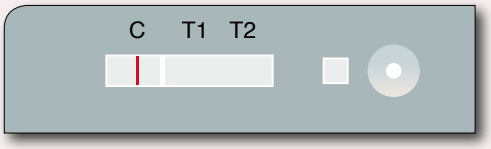


Type H: Guide to results of generic vom[1]-Pf malaria RDTs

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

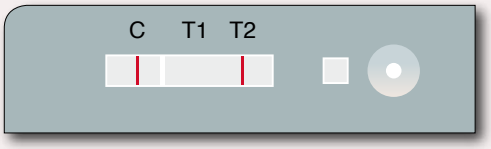


Negative results: Only one line 'C' appears in the results window.

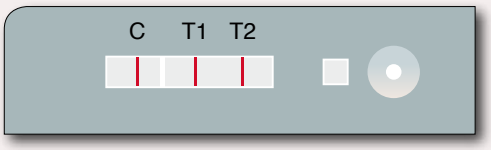


Positive results:

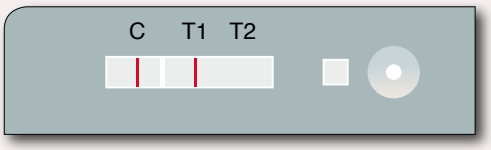
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



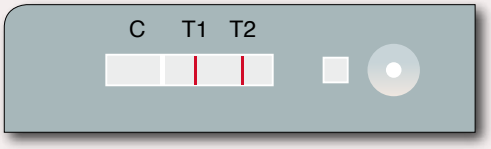
P. falciparum mixed infection (with *P. vivax*, *P. ovale* and/or *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

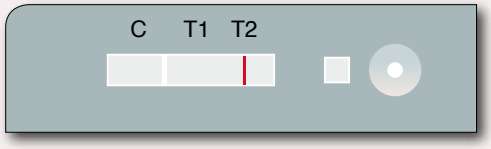


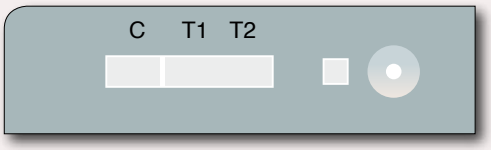
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection. Two lines 'C' and 'T1' appear in the results window.

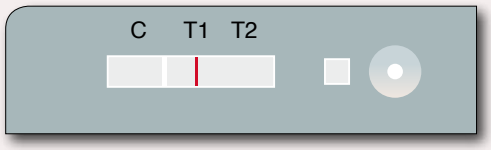


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.





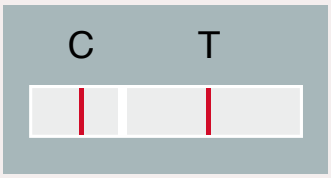




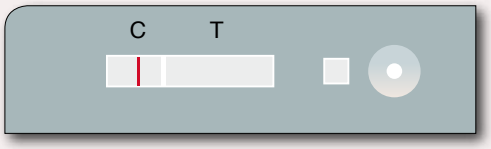
[1] vom, *P. vivax*, *P. ovale*, *P. malariae*

Type I: Guide to results of generic Pv malaria RDTs

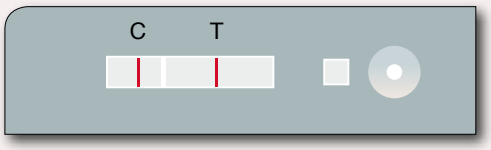
Results window: C=control line; T=test line with bound *P. vivax*-specific pLDH.



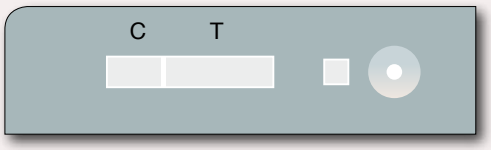
Negative results: Only one line 'C' appears in the results window.

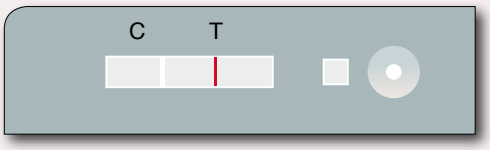


Positive results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



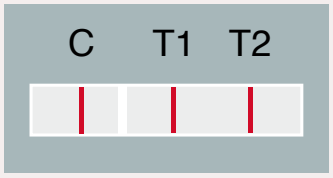
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



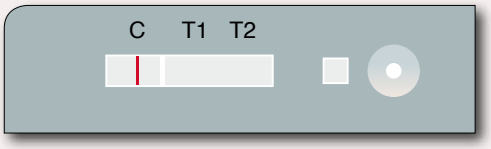


Type J: Guide to results of generic Pf-Pf malaria RDTs

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

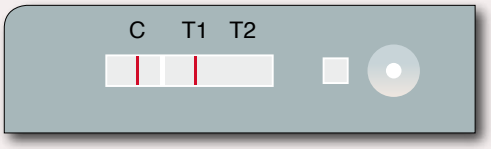


Negative results: Only one line 'C' appears in the results window.

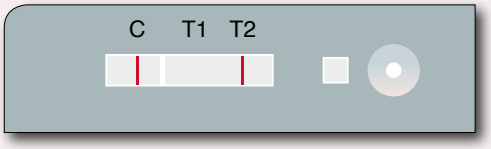


Positive results:

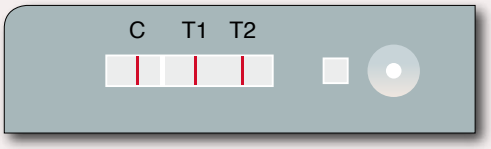
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



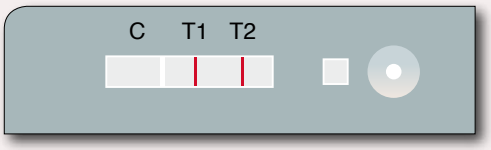
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.

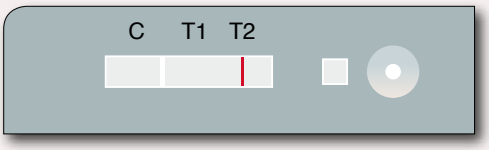


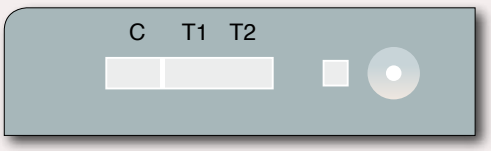
P. falciparum infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

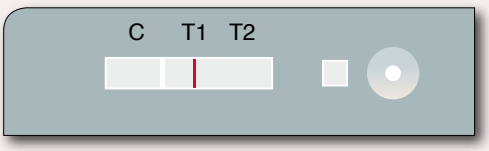


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



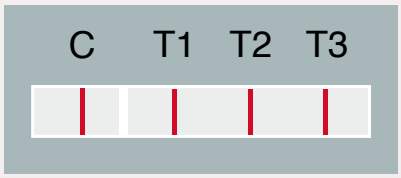




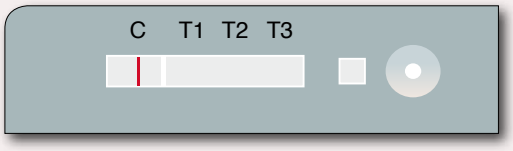


Type K: Guide to results of generic Pv-Pf-Pf malaria RDTs

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).

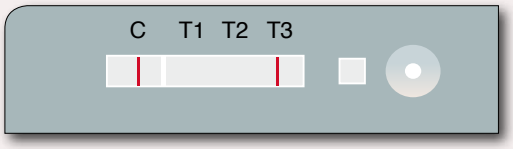


Negative results: Only one line 'C' appears in the results window.

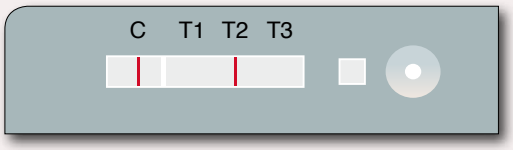


Positive results:

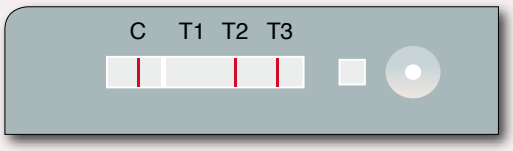
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



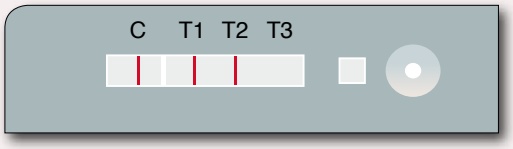
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



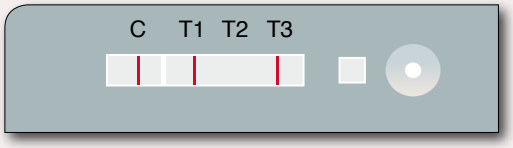
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



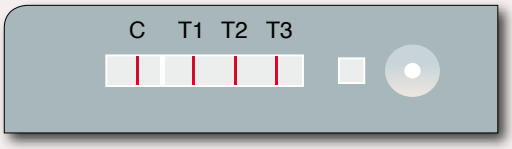
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



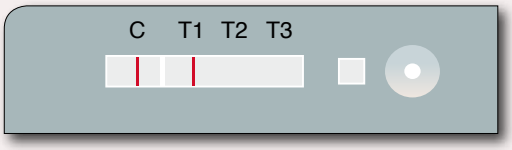
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T3' appear in the results window.



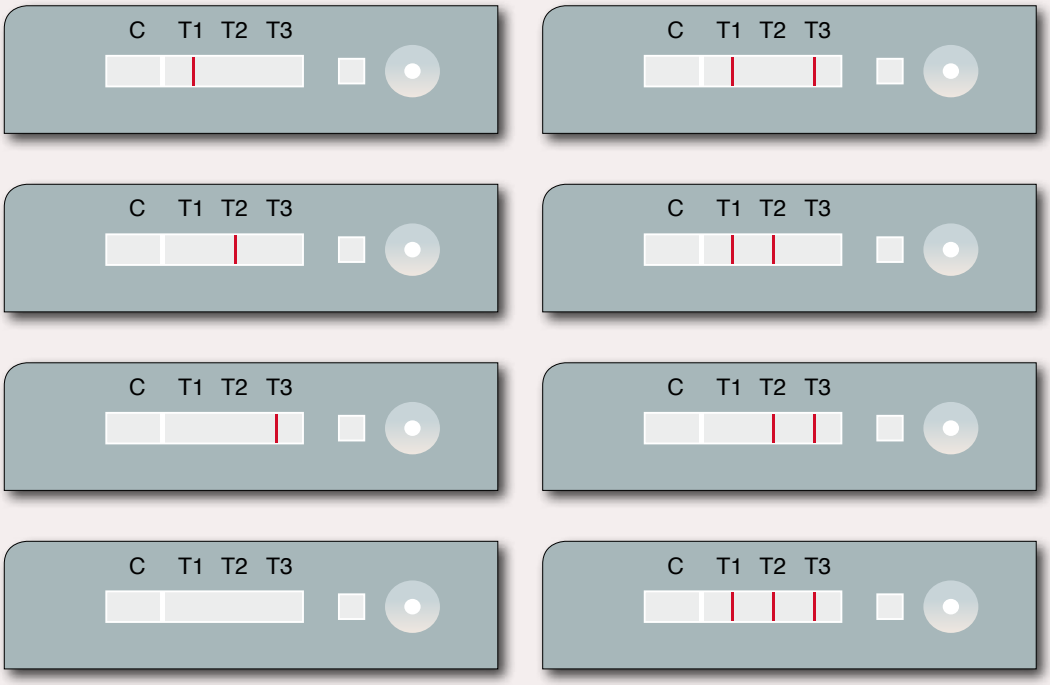
P. falciparum infection and *P. vivax* mixed infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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

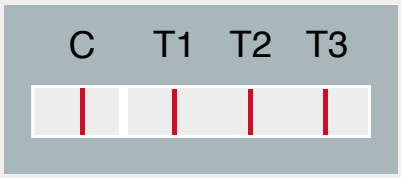


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

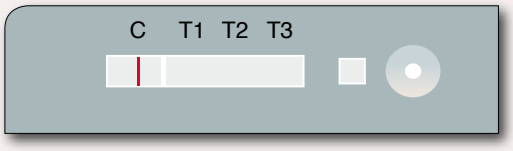


Type L: Guide to results of generic pan-Pf-Pf malaria RDTs

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)

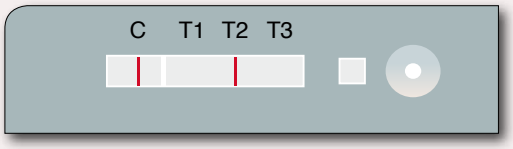


Negative results: Only one line 'C' appears in the results window.

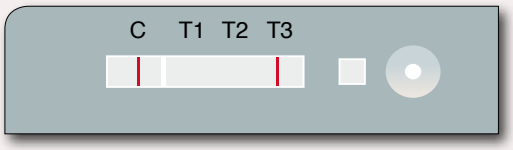


Positive results:

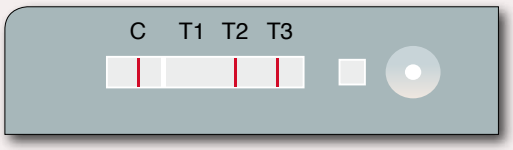
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



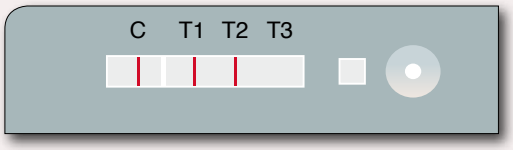
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



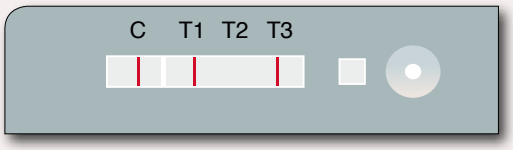
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



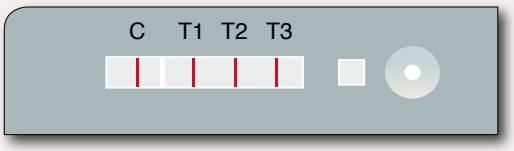
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T2' appear in the results window.



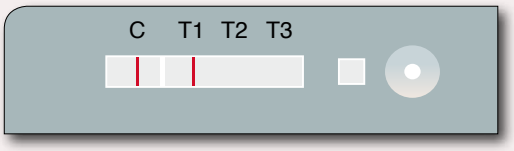
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



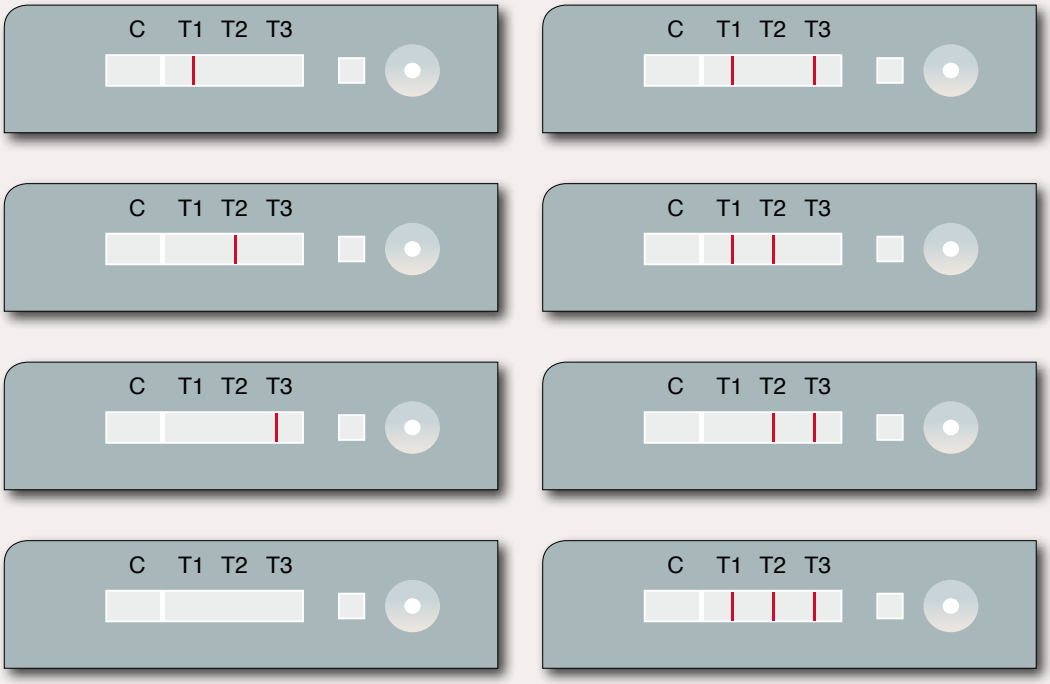
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	20	20	20	20	20	20	20	20
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	20	20	20	20	20	20	20	20
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	20	20	20	20	20	20	20	20
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	20	20	20	20	20	20	20	20
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	20	20	20	20	20	20	20	20
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	20	20	20	20	20	20	20	20
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	20	20	20	20	20	20	20	20
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	20	20	20	20	20	20	20	20
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	20	20	20	20	20	20	20	20
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	20	20	20	20	20	20	20	20
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	20	20	20	20	20	20	20	20
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	20	20	20	20	20	20	20	20
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	20	20	20	19	20	19	20	20
PALUTOP + pf®	5531	ALLDIAG SA	20	20	20	20	20	20	20	20
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	18	19	17	19	20	19	20	20
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	20	20	20	20	20	20	20	20
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	18	20	18	20	20	20	20	20
Pf and Pan										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	20	18	18	17	18	16	20	19 (19)
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	20	20	20	20	20	20	20	20
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	18	16	16	20	19	19	20	20
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	20	20	20	20	20	20	20	20
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	20	20	20	18	18	16	20	20
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	20	20	20	20	20	20	20	20
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	20	20	20	20	20	20	20	20
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	20	20	20	20	20	20	20	20
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	20	20	20	20	20	20	20	20
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	20	20	20	20	20	20	20	20

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
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	20	20	20	20	20	20	20	20
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	20	20	20	20	20	20	20	19
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	20	20	20	20	20	20	20	20
Pf and Pv										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	20	20	20	20	20	20	20	20
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	18 (19)	19 (19)	17 (18)	18	17	16	20	20
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	20	20	20	20	20	20	20	20
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	20	20	20	20	20	20	20	20
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	20	20	20	20	20	20	20	20
Malaria Pf/PAN Test	PROPMALPFPV001	Real World Diagnostics	20	20	20	20	20	20	20	20
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	20	20	20	20	20	20	20	20
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	19 (19)	20	19 (19)	18	20	18	20	20
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	20	20	20	20	20	20	20	20
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	20	20	20	20	20	20	20	20
Pf, Pv and Pan										
PALUTOP +4 optima®	5499	ALLDIAG SA	20	20	20	20	20	20	20	20

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																						
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0.0	26.3	61.3	12.5	0.0	0.0	0.0	2.5	42.5	55.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.0	7.5	52.5	30.0	10.0	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.0	0.0	8.8	41.3	50.0	0.0	0.0	0.0	0.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0.0	7.5	65.0	21.3	6.3	0.0	0.0	7.5	20.0	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.0	0.0	25.0	53.8	21.3	0.0	0.0	0.0	0.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0.0	0.0	18.8	43.8	37.5	0.0	0.0	0.0	0.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0.0	1.3	38.8	43.8	16.3	0.0	0.0	0.0	2.5	97.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			38.8	48.8	12.5	0.0	0.0	2.5	17.5	77.5	2.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0.0	0.0	17.5	48.8	33.8	0.0	0.0	0.0	2.5	97.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0.0	16.3	70.0	11.3	2.5	0.0	0.0	0.0	20.0	80.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	0.0	0.0	47.5	40.0	12.5	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	10.0	61.3	25.0	3.8	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	50.0	40.0	10.0	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0.0	6.3	48.8	30.0	15.0	0.0	0.0	0.0	22.5	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	11.3	61.3	26.3	1.3	0.0	0.0	2.5	27.5	70.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	1.3	43.8	51.3	3.8	0.0	0.0	2.5	5.0	42.5	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	41.3	42.5	16.3	0.0	0.0	0.0	0.0	100.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	5.0	45.0	48.8	1.3	0.0	0.0	0.0	10.0	25.0	65.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	0.0	36.3	58.8	5.0	0.0	0.0	2.5	5.0	30.0	62.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	2.5	2.5	65.0	28.8	1.3	0.0	0.0	2.5	20.0	77.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																						
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	8.8	45.0	43.8	2.5	0.0	2.5	0.0	17.5	30.0	50.0	98.8	1.3	0.0	0.0	0.0	17.5	77.5	5.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.0	1.3	58.8	31.3	8.8	0.0	0.0	0.0	7.5	92.5	76.3	23.8	0.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	12.5	70.0	16.3	1.3	0.0	0.0	0.0	27.5	72.5	96.3	3.8	0.0	0.0	0.0	5.0	72.5	22.5	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	6.3	57.5	26.3	10.0	0.0	0.0	0.0	5.0	95.0	56.3	43.8	0.0	0.0	0.0	0.0	20.0	80.0	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	5.0	5.0	62.5	21.3	6.3	0.0	0.0	10.0	10.0	80.0	41.3	57.5	1.3	0.0	0.0	0.0	7.5	92.5	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	28.8	47.5	23.8	0.0	0.0	0.0	0.0	100.0	50.0	48.8	1.3	0.0	0.0	0.0	2.5	97.5	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	12.5	70.0	16.3	1.3	0.0	0.0	0.0	27.5	72.5	96.3	3.8	0.0	0.0	0.0	0.0	50.0	50.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.0	0.0	41.3	45.0	13.8	0.0	0.0	0.0	5.0	95.0	31.3	68.8	0.0	0.0	0.0	0.0	0.0	95.0	5.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0	0.0	45.0	36.3	18.8	0.0	0.0	0.0	0.0	100.0	8.8	83.8	7.5	0.0	0.0	0.0	0.0	60.0	40.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.0	2.5	48.8	30.0	18.8	0.0	0.0	0.0	5.0	95.0	96.3	3.8	0.0	0.0	0.0	17.5	67.5	15.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	2.5	57.5	30.0	10.0	0.0	0.0	0.0	5.0	95.0	20.0	77.5	2.5	0.0	0.0	0.0	2.5	97.5	0.0	0.0

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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0.0	1.3	43.8	31.3	23.8	2.5	0.0	0.0	2.5	95.0	38.8	51.3	8.8	1.3	0.0	2.5	22.5	75.0	0.0	0.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0.0	0.0	40.0	40.0	20.0	0.0	0.0	0.0	0.0	100.0	81.3	18.8	0.0	0.0	0.0	0.0	15.0	85.0	0.0	0.0
Pf and Pv																						
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.0	5.0	61.3	28.8	5.0	0.0	0.0	2.5	5.0	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	10.0	62.5	26.3	1.3	0.0	0.0	0.0	32.5	65.0	2.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0	8.8	73.8	16.3	1.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	2.5	52.5	28.8	16.3	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.0	5.0	58.8	23.8	12.5	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	50.0	28.8	21.3	0.0	0.0	0.0	2.5	97.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	48.8	41.3	10.0	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf/PAN Test	PROPMALPFPV001	Real World Diagnostics	0.0	0.0	50.0	33.8	16.3	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	11.3	62.5	23.8	2.5	0.0	0.0	2.5	25.0	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	3.8	22.5	60.0	13.8	0.0	0.0	2.5	5.0	42.5	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0.0	12.5	63.8	23.8	0.0	0.0	0.0	0.0	30.0	70.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	61.3	30.0	8.8	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pv and Pan																						
PALUTOP +4 optima®	5499	ALLDIAG SA	0.0	0.0	41.3	43.8	15.0	0.0	0.0	0.0	5.0	95.0	22.5	72.5	5.0	0.0	0.0	0.0	0.0	70.0	30.0	0.0

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 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																		
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	87	89	87	84	85	81	100	100	NA	NA	NA	NA	NA	NA	NA	NA
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	98	97	95	97	98	96	100	99	NA	NA	NA	NA	NA	NA	NA	NA
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	100	99	99	98	100	98	100	100	NA	NA	NA	NA	NA	NA	NA	NA
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	98	98	97	96	97	95	100	100	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	100	99	99	99	98	97	99	100	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	98	99	97	99	99	98	100	100	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line	RMSM-05071	Access Bio, Inc.	95	96	94	98	99	98	99	100	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	98	98	96	98	98	97	100	100	NA	NA	NA	NA	NA	NA	NA	NA
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	93	90	88	91	92	88	99	100	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	97	96	95	99	97	97	100	100	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	94	90	87	91	90	87	100	99	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	96	93	91	96	95	93	100	100	NA	NA	NA	NA	NA	NA	NA	NA
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	88 (99)	90	87 (99)	92	90	88	100	99	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	97	96	96	97	95	94	100	100	NA	NA	NA	NA	NA	NA	NA	NA
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	79	87	78	83	84	79	99	100	NA	NA	NA	NA	NA	NA	NA	NA
PALUTOP + pf®	5531	ALLDIAG SA	95	95	93	100	98	98	99	100	NA	NA	NA	NA	NA	NA	NA	NA
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	84	81	77	82	86	80	100	100	NA	NA	NA	NA	NA	NA	NA	NA
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	83	87	80	85	84	81	100	100	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	96	94	94	94	94	92	100	100	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	81	77	75	77	77	73	100	100	24	26	22	29	23	21	35	35
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	90	90	88	92	89	88	99	99	35	35	35	32	35	32	35	35
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	78	76	73	78	83	76	98	97	28	32	28	29	30	27	35	35
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	93 (99)	93	89 (99)	94	95 (99)	93 (99)	99	99	35	35	35	35	35	35	35	35
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	98 (99)	98	97 (99)	95	98	94	98	100	33	34	32 (34)	34 (34)	35	34 (34)	35	35
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	92 (99)	93	90 (99)	94	94	93	100	99	35	35	35	35	35	35	35	35
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	90	91	89	88	87	85	100	100	34	34	33	33	32	31	35	35

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 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
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	99	97	97	97	98	97	99	100	35	34	34	35	35	35	34	34
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	87	85	78	90	88	83	100	100	2	1	0	1	1	0	29	26
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	97	96	95	97	97	96	99	100	35	35	35	35	33	33	35	34
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	94	92	90	92	89	87	99	99	21	21	17	17	19	15	35	35
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	98	95	95	95	95	94	99	100	35	35	35	35	35	35	35	35
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	97	97	95	95 (99)	95	93 (99)	99	99	24	22 (34)	16 (34)	25	20	18	33	34
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	96	95	94	97	94	93	100	100	35	35	35	35	35	35	35	35
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	99	97	96	97	94	93	100	98	35	35	35	34	35	34	35	34 (34)
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	85 (99)	89 (99)	82 (98)	88	88	82	97 (99)	99	35	34 (34)	34 (34)	35	35	35	35	33 (33)
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	94	89	89	92	86	86	99	100	34	35	34	33	34	32	35	34 (34)
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	96	98	95	97	96	95	100	100	35	34	34	35	35	35	35	35
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	94	91	90	98	95	95	99	100	35	35	35	35	35	35	35	35
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	97	97	94	96	97	95	100	100	35	35	35	33	33	31	35	35
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	96	94	92	94	93	90	99 (99)	99	33	30	29	27	29	23	35	35
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	90 (99)	90	88 (99)	90	90	87	100	99	7	4	1	11	7	5	6	6
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	94	97	94	96	95	94	100	100	30	30	28	29	29	27	35	35
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	85	85	82	85	83	80	100	100	34	33	33	31	34	31	35	35
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	91	91	87	87	86	83	100	99	34	35	34	31	35	31	35	35
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	92	93	91	89	88	86	99	99	35	32	32	34	32	32	35	35
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	94	93	92	96	94	94	99	100	30	32	30	32	33	31	35	35

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* high parasite density dilution samples were at 5000 parasites/µL rather than 2000

[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 scores (0–4) 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																																
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	13.8	25.0	34.0	21.8	5.5	0.0	1.5	18.5	24.0	56.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	2.5	14.0	39.5	29.8	14.3	0.5	1.5	5.0	24.0	69.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.8	4.5	22.5	28.8	43.5	0.0	0.5	0.0	9.0	90.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	2.8	20.5	38.8	31.0	7.0	0.0	0.5	11.0	27.0	61.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	1.0	10.8	27.3	37.3	23.8	0.5	0.0	2.5	22.5	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	1.3	9.0	26.8	26.8	36.3	0.0	0.0	2.5	13.5	84.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	3.0	15.0	26.0	28.3	27.8	0.5	0.0	4.0	14.5	81.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			46.8	34.5	18.8	0.0	0.0	5.0	30.5	63.5	1.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	2.0	7.5	26.8	26.3	37.5	0.0	0.5	1.0	10.0	88.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	8.5	25.0	40.3	21.5	4.8	0.5	1.0	16.5	26.0	56.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	2.8	13.3	31.8	29.0	23.3	0.0	0.0	4.0	19.5	76.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	8.8	18.8	28.3	29.8	14.5	0.5	1.0	7.5	18.5	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	5.0	15.5	35.8	25.3	18.5	0.0	0.0	9.5	20.0	70.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	9.8 (399)	12.0 (399)	29.6 (399)	29.8 (399)	18.8 (399)	0.5	0.5	6.5	26.0	66.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	3.8	18.8	38.5	30.8	8.3	0.0	0.5	7.5	30.0	62.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	16.8	27.0	35.5	17.5	3.3	0.5	2.0	21.0	28.0	48.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
PALUTOP + pf®	5531	ALLDIAG SA	3.0	12.3	29.3	28.5	27.0	0.5	0.5	4.5	18.0	76.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	16.8	33.3	33.8	14.5	1.8	0.0	4.0	22.5	25.5	48.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	15.3	33.8	33.8	15.5	1.8	0.0	4.5	22.5	25.0	48.0	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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	5.5	18.5	35.3	33.8	7.0	0.0	0.5	11.0	27.0	61.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pan																																
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	22.0	27.3	36.5	13.0	1.3	0.0	5.5	22.0	24.5	48.0	95.8	4.3	0.0	0.0	0.0	16.5	58.5	25.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	9.8	14.0	31.8	36.0	8.5	1.0	0.5	9.5	28.5	60.5	50.3	44.8	5.0	0.0	0.0	3.0	10.0	67.5	19.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	21.3	29.8	40.0	8.8	0.3	2.5	3.0	26.0	33.5	35.0	79.3	20.0	0.8	0.0	0.0	6.0	38.5	51.5	4.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	5.8 (399)	22.6 (399)	26.3 (399)	32.3 (399)	13.0 (399)	1.0	1.0	7.5	20.0	70.5	42.0	52.0	6.0	0.0	0.0	2.5	10.0	67.5	19.0	1.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	2.8	20.3	40.3	28.0	8.8	1.0	0.5	10.5	25.0	63.0	28.0	58.5	13.5	0.0	0.0	2.0	6.0	75.0	15.0	2.0	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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	6.5 (399)	11.3 (399)	25.6 (399)	27.8 (399)	28.8 (399)	0.5	0.5	4.0	16.5	78.5	52.3	41.5	6.3	0.0	0.0	3.5	16.5	62.0	18.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	11.0	23.5	36.0	23.3	6.3	0.0	2.5	12.0	23.5	62.0	81.8	18.0	0.3	0.0	0.0	5.0	39.0	53.0	3.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	2.3	10.3	25.8	39.5	22.3	0.5	0.0	3.5	23.0	73.0	14.8	62.5	22.8	0.0	0.0	2.0	2.0	50.0	40.5	5.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	12.5	45.3	35.5	6.8	0.0	0.0	1.0	38.0	42.0	19.0	87.0	13.0	0.0	0.0	0.0	9.0	58.5	32.5	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	3.3	14.0	26.3	26.5	30.0	0.5	0.0	3.0	13.0	83.5	9.8	55.8	33.8	0.8	0.0	1.0	1.0	43.5	45.5	9.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	8.3	14.3	32.8	25.0	19.8	1.0	1.0	5.0	21.0	72.0	81.5	15.8	2.8	0.0	0.0	4.5	36.0	55.0	4.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	4.3	17.5	28.3	32.3	17.8	0.5	1.0	3.5	22.5	72.5	14.5	74.0	11.5	0.0	0.0	2.0	3.5	70.0	22.5	2.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	4.0	15.5	31.3	31.8	17.5	1.0	0.5	4.0	22.0	72.5	58.3	35.3	6.5	0.0	0.0	2.5	29.0	62.0	6.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	4.5	11.5	31.0	29.3	23.8	0.0	0.0	5.5	19.0	75.5	61.8	36.3	2.0	0.0	0.0	2.5	20.0	70.0	7.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																																
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	3.3	16.0	35.3	31.5	14.0	1.0	0.5	4.5	25.0	69.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.0	1.0	0.0	0.0	0.0	99.0	0.5	0.0	0.0	0.5
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	12.3 (399)	56.1 (399)	31.6 (399)	0.0 (399)	0.0 (399)	2.0	2.0	33.0	53.0	10.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.0	1.0	0.0	0.0	0.0	99.0	1.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	9.8	22.0	35.0	25.8	7.5	0.5	1.0	13.5	21.0	64.0	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
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	3.3	18.5	24.8	27.0	26.5	0.0	0.5	3.0	15.0	81.5	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
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	5.5	19.0	29.5	25.0	21.0	0.5	0.0	8.0	17.5	74.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.3	1.8	0.0	0.0	0.0	98.0	2.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	3.3	15.5	23.0	27.3	31.0	0.0	0.5	2.5	12.5	84.5	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
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	5.8	15.0	37.0	26.8	15.5	1.0	0.0	10.5	20.5	68.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0	99.5	0.0	0.0	0.5	0.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	9.8 (399)	12.0 (399)	29.6 (399)	29.8 (399)	18.8 (399)	0.5	0.5	6.5	18.0	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	77.8	20.3	2.0	0.0	0.0	7.5	29.0	59.5	4.0	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	4.5	23.3	34.5	27.3	10.5	0.0	2.0	6.0	29.0	63.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.8	0.2	0.0	0.0	0.0	99.0	1.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	15.5	24.0	34.3	23.5	2.8	0.0	1.5	21.0	31.5	46.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.5	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	11.3	25.0	33.5	27.3	3.0	0.5	2.0	12.5	36.0	49.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	60.3	36.3	3.5	0.0	0.0	72.5	24.5	3.0	0.0	0.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	9.5	13.3	31.5	37.8	8.0	1.0	0.5	8.0	29.5	61.0	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
Pf, Pv and Pan																																
PALUTOP +4 optima®	5499	ALLDIAG SA	5.8	12.0	27.3	31.5	23.5	0.5	1.0	3.0	21.0	74.5	14.0	53.3	32.0	0.8	0.0	0.0	3.5	36.0	47.0	13.5	99.3	0.8	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0

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* high parasite density dilution samples were at 5000 parasites/µl rather than 2000

[c] Calculations include invalid tests

Table A4.3: Distribution of test band intensity scores (0–4) 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																																
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	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
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Alere™ Malaria Ag P.f	05FK140-40-0	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
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. 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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f Rapid Card	17912	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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	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 Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	99.3	0.7	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
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			98.6	0.0	0.0	1.4	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
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, 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
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	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
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	95.0	5.0	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
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene 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
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	97.1	2.9	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 HRP2 (P.f) 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
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. 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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
PALUTOP + pf®	5531	ALLDIAG SA	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
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt 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
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	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																																
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	27.1	66.4	6.4	0.0	0.0	0.0	1.4	52.9	42.9	2.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	2.1	39.3	55.7	2.9	0.0	0.0	0.0	11.4	71.4	17.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	15.0	70.7	14.3	0.0	0.0	0.0	0.0	31.4	61.4	7.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	30.0	65.7	4.3	0.0	0.0	0.0	1.4	58.6	40.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	98.6	0.0	0.7	0.7	0.0	100.0	0.0	0.0	0.0	0.0	2.9	17.9	75.0	4.3	0.0	0.0	0.0	4.3	60.0	35.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	39.3	58.6	2.1	0.0	0.0	0.0	4.3	54.3	41.4	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
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	5.0	67.1	27.1	0.7	0.0	0.0	0.0	28.6	60.0	11.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	99.3	0.0	0.7	0.0	0.0	97.1	1.4	1.4	0.0	0.0	0.0	10.7	73.6	15.0	0.7	0.0	0.0	1.4	30.0	68.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	96.4	3.6	0.0	0.0	0.0	21.4	50.0	25.7	2.9	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	1.4	0.7	61.4	33.6	2.9	1.4	0.0	0.0	5.7	92.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	44.3	46.4	8.6	0.7	0.0	0.0	4.3	61.4	32.9	1.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	11.4	79.3	7.1	2.1	0.0	0.0	4.3	32.9	62.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	96.4	3.6	0.0	0.0	0.0	95.7	4.3	0.0	0.0	0.0	31.4	53.6	15.0	0.0	0.0	0.0	11.4	65.7	22.9	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	39.3	58.6	2.1	0.0	0.0	0.0	14.3	64.3	21.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv																																
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	100.0	0.0	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	0.7	12.9	77.9	8.6	0.0	1.4	0.0	2.9	40.0	55.7
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	100.0	0.0	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	0.7	0.0	49.3	48.6	1.4	2.9	0.0	0.0	1.4	95.7
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	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	2.9	47.1	49.3	0.7	0.0	1.4	0.0	14.3	71.4	12.9
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	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	0.7	32.9	60.7	5.7	0.0	0.0	0.0	7.1	40.0	52.9
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, 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	0.0	2.1	65.7	28.6	3.6	0.0	0.0	0.0	5.7	94.3
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, 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	2.9	32.1	60.0	4.3	0.7	0.0	0.0	8.6	32.9	58.6
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene 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	15.0	65.0	20.0	0.0	0.0	0.0	0.0	38.6	51.4	10.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	95.7	4.3	0.0	0.0	0.0	92.9	7.1	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	79.3	18.6	2.1	0.0	0.0	82.9	15.7	0.0	1.4	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) 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	15.7	70.0	14.3	0.0	0.0	0.0	0.0	44.3	45.7	10.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	99.3	0.7	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	5.7	51.4	40.0	2.9	0.0	0.0	0.0	8.6	71.4	20.0
QuickProfile™ Malaria Pf/Pv Antigen 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	3.6	67.9	28.6	0.0	0.0	0.0	0.0	45.7	48.6	5.7
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	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	5.0	42.9	48.6	3.6	0.0	0.0	0.0	11.4	71.4	17.1
Pf, Pv and Pan																																
PALUTOP +4 optima®	5499	ALLDIAG SA	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	18.6	70.7	10.0	0.7	0.0	0.0	0.0	32.9	67.1	9.3	49.3	39.3	2.1	0.0	0.0	0.0	21.4	38.6	40.0

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								
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	1.4	0.0	0.7	2.9	0.0	1.4
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0.0	2.9	1.4	0.0	0.0	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	5.7	4.3	5.0	2.9	0.0	1.4
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0 (69)	0.0 (139)	0.0	0.0	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	2.9	2.9	2.9	2.9	0.0	1.4
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0.0	1.4	0.7	0.0	0.0	0.0
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan								
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	2.9 (69)	0 (69)	1.4 (138)	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	1.4	0.0	0.7	2.9	2.9	2.9
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.0	1.4	0.7	0.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.0	0.0	0.0	0.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	4.3 (69)	2.9	3.6 (139)	5.7	2.9	4.3
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	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)
Pf and Pv								
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.0	0.0	0.0	0.0	2.9 (34)	1.4 (69)
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0.0 (69)	0.0	0.0 (139)	0.0	3.0 (33)	1.5 (68)
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0	0.0	0.0	0.0	0.0 (34)	0.0 (69)
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	7.1	1.4	4.3	8.6	5.7	7.1
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	1.4	0.0	0.7	2.9	0.0	1.4
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan								
PALUTOP +4 optima®	5499	ALLDIAG SA	0.0	1.4	0.7	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 and Pan								
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60Al-40	Alere Medical Private Limited	2.5	0.0	1.3	1.0	1.0	1.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	1.0	1.5	1.3	2.0	2.0	2.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.5	0.5 (199)	0.5 (399)	1.0	1.0	1.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0.0 (199)	0.5	0.3 (399)	2.0	0.0	1.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	1.0	0.5
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	1.0	0.5	0.8	1.0	0.0	0.5
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	1.0	1.5	1.3	1.0	0.0	0.5
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.0	0.5	0.3	1.0	1.0	1.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	1.0	3.0	2.0	1.0	0.0	0.5
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0.5	1.0 (199)	0.8 (399)	1.0	1.0	1.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pv								
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	1.5	0.5	1.0	1.0	1.0	1.0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	1.0 (199)	1.0	1.0 (399)	1.0 (99)	1.0	1.0 (199)
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	1.5	2.0	1.8	2.0	2.0	2.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0 (99)	1.0	0.5 (199)
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	21.5	23.0	22.3	92.0	93.0	92.5
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.5	0.0	0.3	1.0	1.0	1.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	1.0	0.0	0.5	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	45.0	34.5	39.8	24.0	31.0	27.5
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan								
PALUTOP +4 optima® - Pv-pLDH band	5499	ALLDIAG SA	0.0	1.0	0.5	0.0	0.0	0.0
PALUTOP +4 optima® - Pan-pLDH band			1.0	0.5	0.8	1.0	0.0	0.5

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

[a] 3 (3%) of the 100 *P. falciparum* high parasite density dilution samples were at 5000 parasites/µl rather than 2000

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=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=30)	Lot 2 (n=30)	Overall (n=60)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
Pf only											
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	3.7	5.6	4.6
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.9	0.0	0.4	0.0	0.0	0.0	0.0	1.9	0.9
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	1.7 (115)	0.0	0.9 (231)	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	2.6	0.0	1.3	0.0	0.0	0.0	14.8	14.8	14.8
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0.0	0.9	0.4	0.0	0.0	0.0	3.7	5.6	4.6
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0.9	0.0	0.4	0.0	0.0	0.0	3.7	3.7	3.7
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	1.7	0.0	0.9	0.0	3.3	1.7	3.7	3.7	3.7
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0.0	0.0	0.0	0.0	0.0	0.0	1.9	1.9	1.9
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	1.7	1.7	1.7	6.7	0.0	3.3	11.1	9.3	10.2
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	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 Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0.9	0.0 (115)	0.4 (231)	3.3	3.3	3.3	3.7	5.6	4.6
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	7.4	7.4	7.4
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	3.3	1.7	0.0	1.9	0.9
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0	11.1	18.5	14.8
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0	14.8	14.8	14.8
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0.0 (115)	0.0	0.0 (231)	0.0	0.0	0.0	5.6	3.7	4.6
Pf and Pan											
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	3.3	0.0	1.7	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	3.7	0.0	1.9
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.9	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.9	1.7	1.3	3.3	0.0	1.7	1.9	3.7	2.8
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	1.7 (115)	0.9	1.3 (231)	0.0	0.0	0.0	3.7	3.7	3.7
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	0.0	3.3	0.0	1.7	0.0	1.9	0.9
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	0.0	0.0	0.0	3.3	1.7	1.9	3.7	2.8
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	0.9	0.9	0.9	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.0	0.9	0.4	0.0	0.0	0.0	3.7	5.6	4.6
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0 (115)	0.0	0.0 (231)	0.0	0.0	0.0	3.7	5.6	4.6
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	1.7	0.0	0.9	0.0	3.3	1.7	5.6	5.6	5.6
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

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=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=30)	Lot 2 (n=30)	Overall (n=60)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	6.0	1.7	3.9	10.0	13.3	11.7	22.2	24.1	23.1
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0.0	0.9	0.4	0.0	0.0	0.0	1.9	3.7	2.8
Pf and Pv											
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	1.9	3.7	2.8
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0.0 (114)	0.0	0.0 (230)	3.3	0.0	1.7	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0 (115)	0.0 (114)	0.0 (229)	3.3	0.0	1.7	1.9	5.6	3.7
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	3.7	1.9	2.8
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.0	0.0 (115)	0.0 (231)	0.0	0.0	0.0	1.9	1.9	1.9
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	6.7	3.3	1.9	3.7	2.8
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0 (115)	0.0 (231)	0.0 (28)	0.0	0.0 (58)	1.9	0.0	0.9
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	6.0	4.3	5.2	6.7	0.0	3.3	13.0	11.1	12.0
One Step Malaria HRP2/pLDH (P.f/P.v) 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
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	3.3	1.7	1.9	0.0	0.9
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0.0	0.9 (115)	0.4 (231)	0.0	0.0	0.0	3.7	3.7	3.7
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	3.7	0.0	1.9
Pf, Pv and Pan											
PALUTOP +4 optima®	5499	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* 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							
			Chagas		Dengue		Leishmaniasis		Schistosomiasis	
			Lot 1 (n=4)	Lot 2 (n=4)	Lot 1 (n=14)	Lot 2 (n=14)	Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=4)	Lot 2 (n=4)
Pf only										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	12.5	0.0	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	25.0	0.0	7.1	0.0	0.0	0.0	0.0	0.0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	25.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	25.0
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	7.1	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	0.0	0.0	7.1	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.0	25.0	0.0	0.0	0.0	0.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	25.0	25.0	7.1	21.4	12.5	0.0	0.0	0.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	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							
			Chagas		Dengue		Leishmaniasis		Schistosomiasis	
			Lot 1 (n=4)	Lot 2 (n=4)	Lot 1 (n=14)	Lot 2 (n=14)	Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=4)	Lot 2 (n=4)
Pf and Pv										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	25.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0	0.0	7.1	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	25.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0 (3)	0.0	0.0 (13)	0.0	0.0	0.0	0.0	0.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	25.0	0.0	7.1	0.0	0.0	0.0	0.0	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	12.5	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan										
PALUTOP +4 optima®	5499	ALLDIAG SA	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							
			Anti-mouse antibodies		Anti-nuclear antibodies		Rheumatoid factor		Rapid plasma reagin (RPR) positive	
			Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=24)	Lot 2 (n=24)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=12)	Lot 2 (n=12)
Pf only										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	33.3	33.3	0.0	4.2	0.0	0.0	0.0	0.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0.0	16.7	0.0	0.0	0.0	0.0	0.0	0.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	66.7	66.7	0.0	0.0	33.3	33.3	0.0	0.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	33.3	33.3	0.0	4.2	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	33.3	33.3	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	33.3	33.3	0.0	0.0	0.0	0.0	0.0	0.0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	16.7	16.7	0.0	0.0	0.0	0.0	0.0	0.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	50.0	50.0	8.3	0.0	8.3	0.0	0.0	16.7
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	33.3	33.3	0.0	4.2	0.0	0.0	0.0	0.0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	33.3	33.3	0.0	0.0	16.7	16.7	0.0	0.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0.0	16.7	0.0	0.0	0.0	0.0	0.0	0.0
PALUTOP + pf®	5531	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	16.7	66.7	0.0	0.0	41.7	50.0	0.0	0.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	33.3	33.3	0.0	0.0	50.0	50.0	0.0	0.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	50.0	33.3	0.0	0.0	0.0	0.0	0.0	0.0
Pf and Pan										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	33.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	16.7	4.2	0.0	0.0	8.3	0.0	0.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0.0	33.3	0.0	0.0	16.7	0.0	0.0	0.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	8.3	0.0	0.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	16.7	33.3	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0.0	0.0	0.0	0.0	16.7	25.0	0.0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0	33.3	0.0	0.0	16.7	8.3	0.0	0.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	50.0	33.3	0.0	4.2	0.0	0.0	0.0	0.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	33.3	16.7	33.3	25.0	8.3	25.0	8.3	25.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	16.7	33.3	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.8 *(continued)*

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by blood immunological factor							
			Anti-mouse antibodies		Anti-nuclear antibodies		Rheumatoid factor		Rapid plasma reagin (RPR) positive	
			Lot 1 (n=6)	Lot 2 (n=6)	Lot 1 (n=24)	Lot 2 (n=24)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=12)	Lot 2 (n=12)
Pf and Pv										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.0	33.3	0.0	0.0	0.0	0.0	8.3	0.0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	16.7	33.3	0.0	4.2	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	33.3	16.7	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	16.7	16.7	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	16.7	33.3	0.0	0.0	0.0	0.0	0.0	0.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	16.7	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	16.7	0.0	12.5	16.7	25.0	0.0	0.0	16.7
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	4.2	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	33.3	33.3	0.0	0.0	0.0	0.0	0.0	0.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	33.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan										
PALUTOP +4 optima®	5499	ALLDIAG SA	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 non-Pf test lines on samples containing non-*Plasmodium* spp. infectious agents[b]			Percentage of false positive non-Pf test lines on samples containing immunological factors[c]		
			Lot 1 (n=116)	Lot 2 (n=116)	Overall (n=232)	Lot 1 (n=30)	Lot 2 (n=30)	Overall (n=60)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
Pf and Pan											
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	0.9	0.4	0.0	0.0	0.0	0.0	1.9	0.9
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.9
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0.0 (115)	0.9	0.4 (231)	0.0	0.0	0.0	5.6	1.9	3.7
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	4.3	3.4	3.9	0.0	0.0	0.0	0.0	1.9	0.9
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	0.0	0.0	0.0	0.0	0.0	0.0	3.7	3.7	3.7
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	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	1.7	0.9	1.3	3.3	0.0	1.7	13.0	14.8	13.9
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0.0 (115)	0.0	0.0 (231)	0.0	0.0	0.0	5.6	9.3	7.4
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0.9	0.0	0.4	3.3	3.3	3.3	20.4	18.5	19.4
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	3.4	4.3	3.9	16.7	3.3	10.0	5.6	9.3	7.4
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	37.9	27.6	32.8	46.7	46.7	46.7	68.5	81.5	75.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0.0	0.0	0.0	0.0	0.0	0.0	7.4	7.4	7.4
Pf and Pv											
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0.9	0.0	0.4	0.0	0.0	0.0	16.7	14.8	15.7
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0.0 (114)	0.0	0.0 (230)	0.0	0.0	0.0	0.0	0.0	0.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0.0 (115)	0.0 (114)	0.0 (229)	0.0	0.0	0.0	3.7	3.7	3.7
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	5.6	3.7	4.6
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0.0	0.0 (115)	0.0 (231)	0.0	0.0	0.0	11.1	11.1	11.1
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.0	0.9
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0.0	0.0 (115)	0.0 (231)	0.0 (28)	0.0	0.0 (58)	1.9	1.9	1.9
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	19.0	21.6	20.3	20.0	16.7	18.3	37.0	46.3	41.7
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	1.7	0.9	1.3	0.0	0.0	0.0	0.0	0.0	0.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	23.3	22.6 (115)	22.9 (231)	53.3	36.7	45.0	64.8	61.1	63.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pv and Pan											
PALUTOP +4 optima® - Pv-pLDH band	5499	ALLDIAG SA	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
PALUTOP +4 optima® - Pan-pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	3.7	3.7	3.7

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																										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.1	15	0	3.0	15	0	2.5	15	0	2.9	15	0	3.0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.1	15	0	3.0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	15	0	3.9	15	0	4.0	15	0	3.7	15	0	3.6	15	0	3.4	15	0	3.6	15	0	3.9	15	0	3.7
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. 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	2.9	15	0	3.0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	15	0	3.1	15	0	3.3	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.1
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	15	0	3.9	15	0	3.5	15	0	3.9	15	0	3.6	15	0	3.4	15	0	3.4	15	0	3.9	15	0	3.5
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	15	0	2.9	15	0	3.6	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	4.0	15	0	3.1
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			15	0	1.8	15	0	1.0	15	0	1.2	15	0	1.1	15	0	1.4	15	0	1.1	15	0	1.8	15	0	1.1
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	15	0	3.8	15	0	3.4	15	0	4.0	15	0	3.5	15	0	3.6	15	0	3.1	15	0	3.9	15	0	3.4
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	15	0	2.8	15	0	3.0	15	0	2.0	15	0	2.0	15	0	1.6	15	0	2.0	15	0	3.0	15	0	3.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	15	0	3.3	15	0	3.9	15	0	3.5	15	0	3.0	15	0	3.5	15	0	3.1	15	0	3.9	15	0	2.9
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	15	0	3.0	15	0	3.3	15	0	3.0	15	0	3.0	15	0	3.0	14	1	2.9	15	0	3.2	15	0	3.0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	15	0	2.8	15	0	3.4	15	0	3.4	15	0	2.9	15	0	2.8	15	0	3.0	15	0	3.4	15	0	3.0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.2	15	0	2.9
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	15	0	2.3	15	0	2.9	15	0	2.2	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.4	15	0	2.4
PALUTOP + pf®	5531	ALLDIAG SA	15	0	3.0	15	0	3.0	15	0	3.6	15	0	3.0	15	0	3.8	15	0	3.1	15	0	4.0	15	0	3.0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	15	0	1.5	15	0	2.0	15	0	1.9	15	0	2.0	14	1	2.3	15	0	2.0	15	0	2.5	15	0	2.0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt Ltd	15	0	2.0	15	0	2.4	15	0	2.0	15	0	2.0	15	0	2.2	15	0	2.0	15	0	2.1	15	0	2.0
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	15	0	2.8	15	0	3.0	15	0	3.0	15	0	2.7	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.9
Pf and Pan																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	15	0	2.0	15	0	2.4	15	0	2.0	15	0	1.9	15	0	2.0	15	0	1.9	14	0	2.1	15	0	1.9
Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	15	0	2.9	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
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.1	15	0	2.3	15	0	2.0	15	0	2.0	15	0	2.1
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	15	0	2.9	15	0	2.9	15	0	2.9	15	0	2.9	15	0	2.7	15	0	2.9	15	0	3.1	15	0	3.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	15	0	2.8	15	0	3.0	15	0	2.7	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.7	15	0	3.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.3	15	0	3.1	15	0	3.3	15	0	3.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	15	0	3.0	15	0	2.9	15	0	2.9	15	0	2.0	15	0	2.0	14	0	2.0	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	3.4	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	15	0	1.4	15	0	1.5	15	0	1.3	14	0	1.4	15	0	1.3	13	0	1.4	15	0	1.4	15	0	1.6
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	15	0	3.0	15	0	3.6	15	0	3.1	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.9	15	0	3.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	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	2.9
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	15	0	2.9	15	0	2.9	15	0	3.0	13	0	3.0	15	0	3.0	15	0	3.0	15	0	3.7	15	0	2.9
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	15	0	3.1	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.3	15	0	3.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	15	0	3.5	15	0	3.7	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.5	15	0	3.0
Pf and Pv																										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	15	0	2.9	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
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	13	0	1.0	15	0	1.0	15	0	1.0	11	0	1.0	4	1	1.0	13	0	1.0	15	0	1.0	15	0	1.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.0	15	0	2.0	15	0	1.8	15	0	3.0	15	0	3.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	15	0	3.0	15	0	3.0	15	0	3.7	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.6	15	0	2.9
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	15	0	2.6	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.7	15	0	2.9
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	15	0	3.0	15	0	3.1	15	0	3.9	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.7	15	0	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
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	15	0	3.1	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	15	0	3.1	15	0	3.9	15	0	3.4	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.6	15	0	3.1
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	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	3.4	15	0	2.9
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	15	0	2.7	15	0	3.0	15	0	2.7	15	0	2.1	15	0	2.1	15	0	2.0	15	0	2.7	15	0	2.9
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	15	0	2.9	15	0	2.9	15	0	3.0	15	0	2.0	15	0	2.9	15	0	2.9	15	0	2.7	15	0	3.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	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	3.2	15	0	3.0
Pf, Pv and Pan																										
PALUTOP +4 optima®	5499	ALLDIAG SA	15	0	3.0	15	0	3.2	15	0	3.2	15	0	2.9	15	0	3.1	15	0	3.0	15	0	3.9	15	0	3.0

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																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	14	0	1.0	0	0	ND	15	0	1.0	6	0	1.0	10	0	1.0	0	0	ND	7	0	1.0	4	0	1.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0	0	ND	0	0	ND	0	0	ND	0	0	ND	0	0	ND	5	0	1.0	3	0	1.0	0	0	ND
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	10	0	1.0	13	0	1.0	8	0	1.0	7	0	1.0	0	0	ND	3	0	1.0	11	0	1.0	15	0	1.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0	0	ND	15	0	1.0	12	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	10	0	1.0	15	0	1.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	12	0	1.0	12	0	1.0	7	0	1.0	1	0	1.0	0	0	ND	2	0	1.0	8	0	1.0	10	0	1.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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	15	0	1.0	15	0	1.0	6	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0	0	ND	0	0	ND	1	0	1.0	1	0	1.0	0	0	ND	0	0	ND	0	0	ND	0	0	ND
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	13	0	1.0	15	0	1.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	1	0	1.0	0	0	ND	0	0	ND	1	0	1.0	2	0	1.0	2	0	1.0	0	0	ND	0	0	ND
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	14	0	1.0	14	0	1.0	15	0	1.0	13	0	1.0	13	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	6	0	1.0	10	0	1.1	13	0	1.4	13	0	1.2	10	0	1.4	10	0	1.2	4	0	1.3	11	0	1.3
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0	0	ND	0	0	ND	0	0	ND	0	0	ND	1	0	1.0	9	0	1.0	5	0	1.0	0	0	ND
Pf, Pv and Pan																										
PALUTOP +4 optima®	5499	ALLDIAG SA	15	0	1.9	15	0	1.0	15	0	1.6	15	0	1.0	15	0	1.8	15	0	1.0	15	0	2.0	15	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																										
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	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
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	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
Alere™ Malaria Ag P.f	05FK140-40-0	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
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. 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
BioTracer™ Malaria P.f Rapid Card	17912	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
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	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 Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	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
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.6	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS 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
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	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	5	0	4.0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	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 (HRP2) Pf Rapid Test	R-409-50-C	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
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech 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
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) 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 HRP2 (P.f) 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	4.0	5	0	4.0	5	0	4.0	5	0	4.0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0
PALUTOP + pf®	5531	ALLDIAG SA	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
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt 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
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	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 Pan																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical 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
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	5	0	4.0	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
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical 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
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	5	0	4.0	5	0	4.0	5	0	3.6	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	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
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	5	0	2.6	5	0	2.8	5	0	3.0	5	0	3.2	5	0	2.8	5	0	3.2	5	0	2.8	5	0	3.0
CareStart™ Malaria Screen RDT	RMAM-05071	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
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	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
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. 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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	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
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	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
Pf and Pv																										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	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
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	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	2.0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	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 Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	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 Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	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

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
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS 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
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene 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	4.0	5	0	4.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) 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	3.8	5	0	4.0
One Step Malaria HRP2/pLDH (P.f/P.v) 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	4.0	5	0	4.0	5	0	4.0	5	0	4.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. 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
QuickProfile™ Malaria Pf/Pv Antigen 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	4.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	4	1	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Pf, Pv and Pan																										
PALUTOP +4 optima®	5499	ALLDIAG SA	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, *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																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	5	0	2.2	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
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	4	0	1.0	5	0	1.0	5	0	1.6	5	0	2.0	5	0	2.0	5	0	1.2	5	0	2.0	5	0	2.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	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	5	0	2.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	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	5	0	2.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	5	0	1.6	5	0	2.0	5	0	1.8	5	0	1.8	5	0	1.0	5	0	2.0	5	0	1.8	5	0	1.8
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	5	0	1.8	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.2	4	0	1.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	5	0	2.0	5	0	3.0	5	0	2.4	5	0	2.0	5	0	3.0	5	0	2.0	5	0	2.0	5	0	2.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	4	0	1.0	5	0	1.6	5	0	1.2	5	0	1.4	5	0	2.0	5	0	1.8	5	0	1.0	5	0	1.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	5	0	1.2	5	0	1.6	5	0	1.8	5	0	1.0	5	0	2.0	5	0	1.6	5	0	1.0	5	0	1.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	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, Pv and Pan																										
PALUTOP +4 optima®	5499	ALLDIAG SA	5	0	2.8	5	0	2.0	5	0	3.0	5	0	2.0	5	0	3.0	5	0	2.4	5	0	3.0	5	0	2.0

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																		
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	0	0	0	0	2	0	0	0	1	0	0	0	3	0	0	0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PALUTOP + pf®	5531	ALLDIAG SA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0	0	0	0	2	0	0	0	1	0	1	1	1	0	0	0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	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
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	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																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0	0	1	0	0	0	0	0	1	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0	0	0	0	1	0	0	0	0	0	3	0	0	0	0	0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	0	0	0	0	2	0	0	0	0	0	1	0	0	0	1	0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	4	0	2	0	4	0	4	0	3	0	3	1	3	0	3	0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	2	0	1	0	2	0	3	0	3	0	2	0	1	0	3	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	2	0	1	0	1	0	4	0	4	0	3	0	3	0	3	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima® - Pv-pLDH band	5499	ALLDIAG SA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PALUTOP +4 optima® - Pan-pLDH band			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																		
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PALUTOP + pf®	5531	ALLDIAG SA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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	1	0	0	0	0	0	1	0	0	0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	4	0	2	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	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 A4.14: 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																		
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test	ITP11002-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - HRP2 band	RMSM-05071	Access Bio, Inc.	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - Pf-pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA P.F. CASSETTE TEST	ML01	ICT INTERNATIONAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria HRP2 (P.f) Test	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
PALUTOP + pf®	5531	ALLDIAG SA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit f® Ver 1.0 - Dipstick	55IC103-50	ARKRAY Healthcare Pvt Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parahit® f Ver 1.0 - Device	55IC104-50	ARKRAY Healthcare Pvt 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) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pan																		
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pv																		
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	1	0	2	0	2	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	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 (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	1	0	3	0	4	0	8	0	3	0	4	0	1	0	0	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	6	0	5	0	9	0	13	0	10	0	11	0	6	0	8	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	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 (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	3	0	4	0	5	0	5	0	5	0	5	0	5	0	5	0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	0	0	0	0	1	0	2	0	2	0	0	0	0	0	0	0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Pf, Pv and Pan																		
PALUTOP +4 optima®	5499	ALLDIAG SA	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																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	4	0	1.0	4	0	1.0	0	0	0.0	4	0	1.0	4	0	1.0	4	0	1.0	3	0	1.0	4	0	1.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	4	0	2.0	4	0	1.5	4	0	2.0	4	0	1.5	4	0	2.0	4	0	1.5	4	0	1.8	4	0	1.3
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	3	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	0	1.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	1.3	4	0	2.0	4	0	2.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	4	0	2.0	4	0	2.0	3	0	2.0	4	0	2.0	3	0	1.7	4	0	2.0	4	0	2.0	4	0	1.8
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	4	0	1.8	4	0	1.0	4	0	2.0	4	0	1.3	4	0	1.0	4	0	1.0	4	0	2.5	4	0	1.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	4	0	2.0	4	0	1.5	4	0	1.0	4	0	1.8	4	0	1.0	4	0	1.0	4	0	1.5	4	0	1.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	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
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	0	0	0.0	2	0	1.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.5	4	0	2.0	4	0	2.5	4	0	2.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	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	0	1.0	4	0	1.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	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
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	4	0	1.3	4	0	1.5	3	0	1.0	4	0	1.0	1	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	4	0	1.5	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	1.8	4	0	1.5	4	0	2.0
Pf and Pv																										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	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
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	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
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	4	0	2.0	4	0	1.0	4	0	2.0	4	0	1.3	4	0	1.0	4	0	1.0	4	0	2.0	4	0	1.8
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	4	0	2.0	4	0	1.8	4	0	2.0	4	0	1.3	4	0	2.0	4	0	1.5	4	0	2.0	4	0	2.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	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	2.3	4	0	2.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	4	0	2.0	4	0	1.5	4	0	2.0	4	0	1.3	4	0	1.5	4	0	1.0	4	0	2.0	4	0	1.8
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	4	0	1.3	4	0	2.0	4	0	1.8	4	0	1.0	4	0	1.5	4	0	1.3	4	0	1.0	4	0	1.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	0.0	0	0	0.0	0	0	0.0	1	0	1.0	0	0	0.0	3	0	1.0	0	0	0.0	0	0	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.8	4	0	1.0	4	0	1.0	4	0	1.0
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	4	0	1.5	4	0	2.0	4	0	1.8	4	0	1.0	4	0	1.3	4	0	1.0	4	0	2.0	4	0	1.3
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	4	0	1.0	4	0	1.0	4	0	1.8	4	0	1.0	4	0	2.0	4	0	1.0	4	0	1.0	4	0	1.0
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	4	0	2.0	4	0	1.8	4	0	2.0	3	0	1.0	4	0	2.0	4	0	1.5	4	0	1.8	4	0	1.0
Pf, Pv and Pan																										
PALUTOP +4 optima® - Pv-pLDH band	5499	ALLDIAG SA	4	0	2.0	4	0	1.8	4	0	2.0	4	0	1.0	4	0	1.3	4	0	1.8	4	0	2.0	4	0	1.0
PALUTOP +4 optima® - Pan-pLDH band			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	2.8	4	0	2.0

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																										
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	2	0	3.0	2	0	2.5	2	0	2.5	2	0	2.0	2	0	2.5	2	0	3.0	2	0	2.5	2	0	2.0
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	4.0	2	0	3.0	2	0	3.5	2	0	3.0
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	2	0	2.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	ASAN Pharmaceutical Co., Ltd	2	0	4.0	2	0	3.5	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	2	0	4.0	2	0	4.0	2	0	3.5	2	0	3.0	2	0	4.0	2	0	3.0	2	0	4.0	2	0	3.0
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C32RHA25	RapiGEN Inc.	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.0	2	0	3.0	1	0	3.0	2	0	3.0
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	2	0	3.0	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	2	0	4.0	2	0	4.0	2	0	4.0	2	0	2.0	2	0	3.5	2	0	3.0	2	0	3.5	2	0	4.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071	Access Bio, Inc.	1	0	1.0	2	0	1.0	2	0	1.0	2	0	1.0	1	0	1.0	1	0	1.0	0	0	0.0	1	0	1.0
CareStart™ Malaria Screen RDT	RMAM-05071	Access Bio, Inc.	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	4.0	2	0	4.0
ICT MALARIA DUAL TEST	ML03	ICT INTERNATIONAL	2	0	3.0	2	0	2.0	2	0	3.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	3.0	2	0	2.0
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	2	0	3.5	2	0	4.0	2	0	3.5	2	0	2.5	2	0	3.5	2	0	3.5	2	0	4.0	2	0	4.0
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	2	0	2.5	2	0	3.0	2	0	2.5	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0	2	0	2.0
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	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	2	0	3.0
Pf and Pv																										
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	2	0	4.0	2	0	3.5	2	0	4.0	2	0	3.5	2	0	3.5	2	0	3.0	2	0	4.0	2	0	3.5
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	2	0	4.0	2	0	4.0	2	0	4.0	2	0	4.0	1	1	4.0	2	0	4.0	2	0	4.0	2	0	3.5
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	2	0	3.0	2	0	3.0	2	0	3.5	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	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	2.0	2	0	3.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT	RMVM-05072	Access Bio, Inc.	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	4.0	2	0	4.0
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	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	2	0	3.0
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	1	1	2.0	2	0	3.0	2	0	3.0
MD Malaria Pf/Pv (pLDH) Test	MDMALLDH004	Medical Diagnostech (Pty) Ltd	0	0	0.0	0	0	0.0	0	0	0.0	1	0	1.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0	0.0
One Step Malaria HRP2/pLDH (P.f/P.v) Test	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	2	0	3.0	2	0	3.0	2	0	2.5	2	0	2.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.5
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	2.5	2	0	2.0	2	0	3.5	2	0	3.0
QuickProfile™ Malaria Pf/Pv Antigen Test	71050	Lumiquick Diagnostics Inc.	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.0	2	0	2.5	2	0	3.0	2	0	3.0	2	0	2.5
Rapid Test Kit for Malaria Ag Pf/Pv-Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0
Pf, Pv and Pan																										
PALUTOP +4 optima® - Pv-pLDH band	5499	ALLDIAG SA	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	4.0	2	0	3.0
PALUTOP +4 optima® - Pan-pLDH band			2	0	3.0	2	0	4.0	2	0	4.0	2	0	3.0	2	0	4.0	2	0	4.0	2	0	4.0	2	0	4.0

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 (*14–15*). 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]

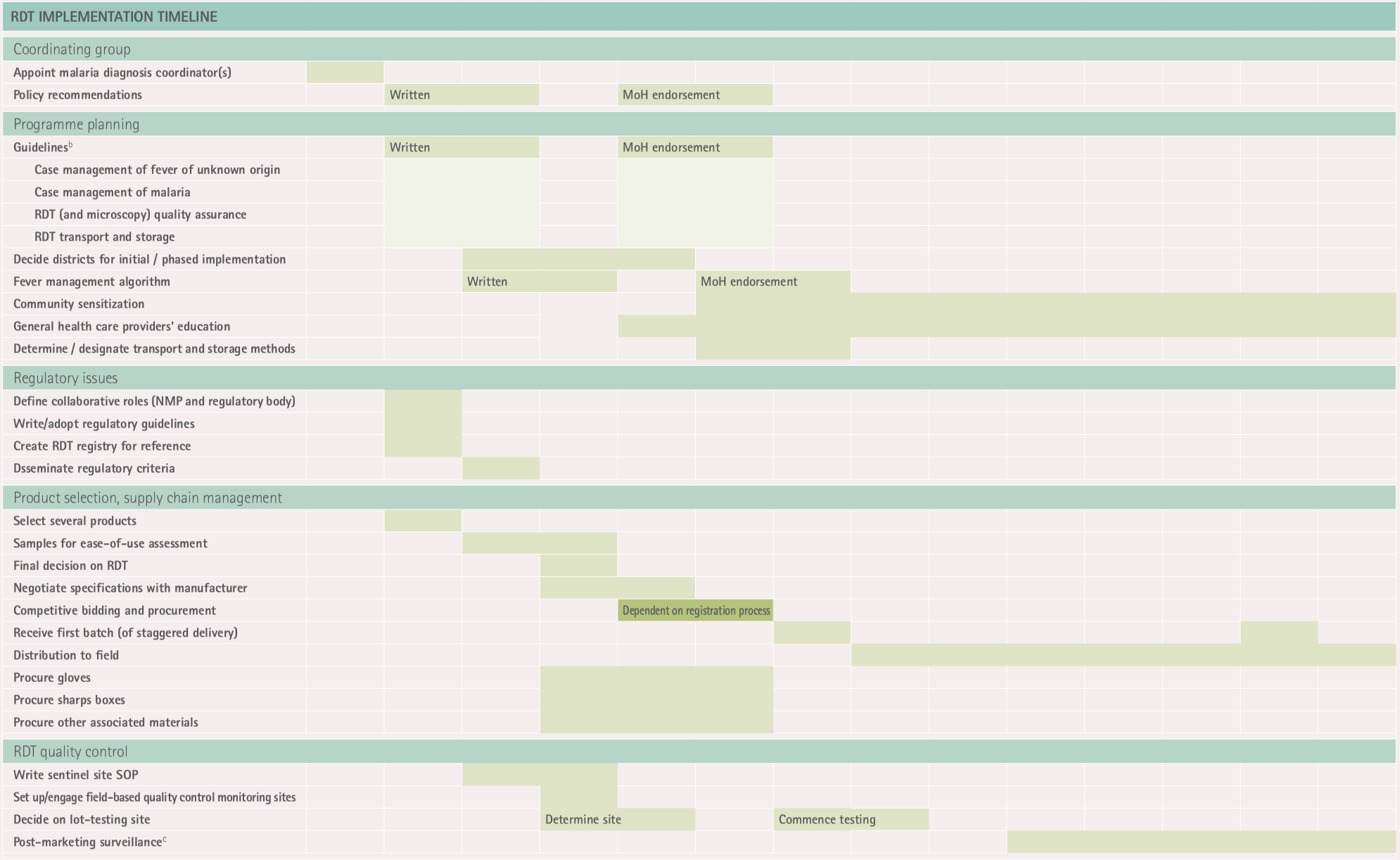
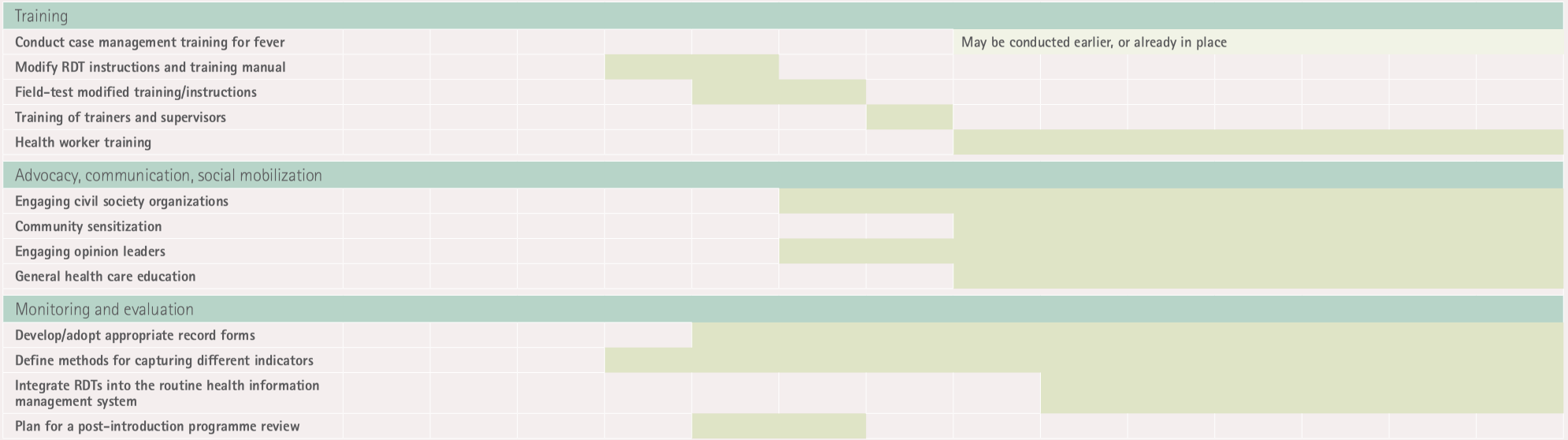


Figure A5.1 *(continued)*



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 (*14*)

[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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