Malaria Rapid Diagnostic Test Performance

Results of WHO product testing of malaria RDTs: round 8 (2016–2018)

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 became a requirement for procurement of all *P. falciparum*-only rapid diagnostic tests (*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 5–8 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 the lot-testing laboratory: the Research Institute for Tropical Medicine, Philippines for products procured for use in India at the National Institute for Malaria Research and in Nigeria at the ANDI Centre of Excellence for Malaria Diagnosis, University of Lagos.

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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Acronyms and 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
IVD	in-vitro diagnostic
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 1–8

1.1 Introduction

WHO estimates that 3.2 billion people are at risk for malaria. In 2016, there were an estimated 216 million new cases (with an uncertainty range of 196 million to 263 million) and an estimated 445 000 deaths (with an uncertainty range of 402 000 to 486 000). Approximately 91% 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 all countries with ongoing malaria transmission have adopted the WHO policy of testing before administering treatment, national surveys between 2014 and 2016 suggest that approximately 70% of cases of suspected malaria in children in sub-Saharan Africa were not confirmed with a diagnostic test, resulting in overuse of antimalarial drugs and poor disease monitoring (*1*).

Since 2010, WHO has recommended 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 last decade. Thus, RDT sales increased from 46 million in 2008 to 320 million in 2013 (according to manufacturer sales data). In 2014, for the second time, the number of diagnostic tests provided (RDTs and microscopy combined) in Africa exceeded the total number of courses of artemisinin-based combination therapy administered.

Since 2009, annual publication of the results of WHO's malaria RDT product testing, a programme for systematic evaluation and comparison of the performance of commercially available malaria RDTs, has formed the basis for the criteria for malaria RDT procurement of WHO, other United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria, national governments and nongovernmental organizations. The data have guided procurement decisions, and these, in turn, have shifted markets towards better-performing tests (*1*) and are driving overall improvements in the quality of manufacture. Although the focus of the programme is on the performance of products in correctly identifying parasites, the results have also yielded a significant body of data on the thermal stability, lot-to-lot variation, anomalies and compliance with best practices on labelling and instructions for use of the tests. Round 8 also included the first comparative data on RDT performance for detection of *P. falciparum* with *pfhrp2/3* gene deletions.

WHO's malaria RDT product testing constitutes the laboratory evaluation component of WHO malaria RDT prequalification, although 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 inspection of manufacturing sites as well as a laboratory evaluation, has been required for procurement of *P. falciparum*-only-detecting malaria RDTs. It is expected that these requirements will be extended to combination RDTs by the end of 2018. Thus, all manufacturers that submitted products to round 8 and will submit to future rounds will be required also to submit applications for WHO prequalification.

This summary presents an overview of the results of rounds 5–8 of malaria RDT product testing and the concepts for understanding and using the results. It is published in conjunction with the release of the full report on round 8. 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 a single data set. The separate, full reports of each round (*3–9*) 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, Special Programme for Research and Training in Tropical Diseases (TDR), FIND, the United States Centers for Disease Control and Prevention (CDC) and other partners. All companies that manufacture RDTs according to the ISO 13485:2003 quality system standard were invited to submit products for evaluation. Starting in round 8, all manufacturers are required to submit a completed pre-submission form to the WHO prequalification programme for in-vitro diagnostics (IVDs). In each round of testing, products were evaluated against geographically diverse, cryopreserved *P. falciparum* and *P. vivax* clinical samples diluted to 200 and 2000 parasites/μL with consistently comparable concentration ranges of histidine-rich protein 2 (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, 46 and 35 products from 13, 23, 27, 34, 22, 27 and 17

manufacturers were evaluated in rounds 2, 3, 4, 5, 6, 7 and 8, respectively. Of these 332 products, 327 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites and a parasite-negative panel. Thermal stability was assessed after two months of storage at elevated temperature and humidity, and a rudimentary assessment of ease of use was made. In rounds 6, 7 and 8, specific observations of RDT anomalies were also systematically recorded. In round 8, testing against a panel of HRP2-negative *P. falciparum* was introduced.

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 327 fully evaluated products in rounds 1–8, 32 have been evaluated twice, 21 have been evaluated three times, five evaluated four times, two evaluated five times and one evaluated six times. Of the 227 unique products tested in the programme, 77 detect *P. falciparum* only, 57 detect and differentiate *P. falciparum* and *P. vivax* malaria, 72 detect *P. falciparum* and the *Plasmodium* genus, 15 products detect *Plasmodium* species only, five products detect *P. falciparum*, *P. vivax* and *Plasmodium* genus, and one product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation. When the same products were resubmitted in subsequent rounds of testing, the second set of results replaced those from the earlier round. Thus, the performance of some tests reported below differs from that reported in rounds 1–7.

Of the 27 products due for compulsory retesting in round 8, two were submitted (Table S1). Round 4 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 the 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 IVDs, 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 determines the eligibility of HRP2-detecting *P. falciparum*-only malaria RDTs for WHO procurement as of 1 January 2018.

To facilitate an eventual full transition to WHO prequalification as a procurement requirement, manufacturers that participated in round 8 and all those that manufacture products that met WHO performance criteria for procurement in previous rounds were required to submit an application for WHO prequalification by 31 December 2017 in order to remain eligible for future procurement.

1.3 Panel detection score and other results of the evaluation

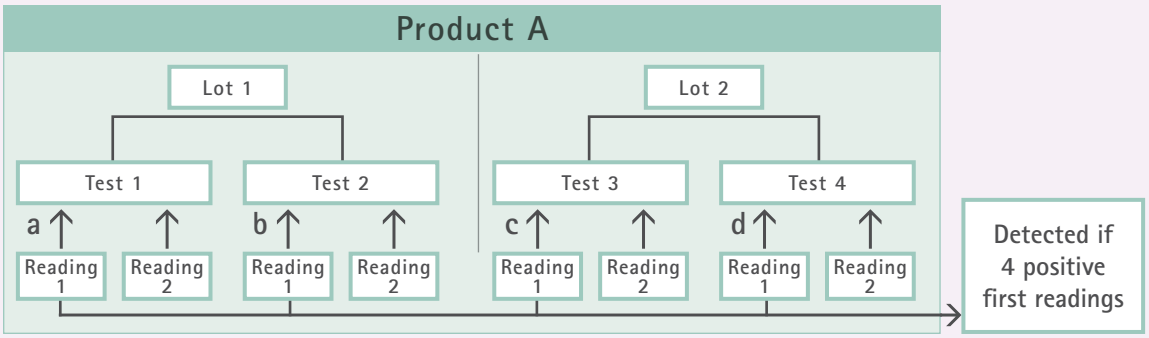
The results (summarized in Figs S1–S3 and Tables S2 and S3) provide comparative data on two lots of products against a panel of parasite samples diluted in blood to a low density (200 parasites/µL) and a higher density (2000 parasites/µL). The former is well below the mean parasite density found in many populations in areas 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 calculated from the percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or by a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density, it must show a positive result in four tests (two RDTs per lot for two lots); at the higher parasite density, it must show a positive result in two tests (one RDT per lot for two lots). Thus, the PDS is a combined measure of positivity rate incorporating inter-test and inter-lot consistency. As all tests performed on each sample must show a positive result for the sample to be considered positive, the PDS for a given RDT will usually be lower than a simple positivity rate per panel, measured by comparing the number of positive tests among all tests performed per panel. The PDS is also different from clinical sensitivity, which is the ability of the test to detect malaria infection in a given population of infected patients. Boxes 1 and 2 illustrate how the PDS is calculated and how it differs from a simple positivity rate for all samples tested and from clinical sensitivity in a population.

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

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.

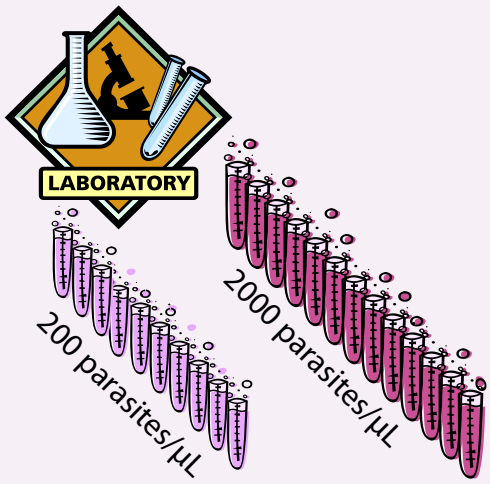
In the above example, the positivity rate is: 9/12 = 75%.

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.

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 previous reports is that the panels used included 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 (Brazil, Colombia, Peru), India, East and Central Africa (Democratic Republic of the Congo, Eritrea, Kenya, Rwanda, Uganda) and West Africa (Ghana and Senegal) do not express HRP2 and/or HRP3 *(12–17)*. In areas where there are *pfhrp2*-deleted parasites, tests for HRP2 will have greatly reduced sensitivity or be incapable of detecting *P. falciparum*. The HRP3 protein is an epitope of HRP2, and, because of its similarity to HRP2, parasites that do not express HRP2 but do express HRP3 can sometimes be detected by HRP2-based RDTs, especially at higher parasite densities *(18)*. WHO recommends use of RDTs that include non-HRP2 antigen targets, e.g. pLDH for *P. falciparum* detection in populations, where ≥ 5% false-negative RDTs are due to *pfhrp2* deletions. In round 8, testing was introduced for all products against a panel of clinical and cultured *P. falciparum* parasites that do not express the HRP2 and HRP3 proteins.

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 used in areas where temperatures rarely rise above 30°C, stability at high temperatures is less important than 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 (*19*). Evaluation of adherence to the recommendations was introduced in round 7 and will continue through WHO prequalification dossier review.

Detailed results can be found in the report of each evaluation (*3–9*) and at http://www.who.int/malaria/publications/diagnostic_testing/en/ (accessed 10 May 2018).

1.4 Summary of outcomes

Laboratory 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, to guide United Nations procurement policy and to support WHO procedures for prequalification of IVDs.

In round 8, the proportion of tests that achieved a PDS ≥ 75% at a density of 200 parasites/µL was slightly higher than in round 7 for *P. falciparum* (88.2%) and substantially higher for *P. vivax* (91.7%).

Several RDTs in the eight 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 (Figs S1–S3).

Although the performance of the products in round 8 varied at low parasite density (200 parasites/µL), four of 34 products had a PDS < 75%, and the rate of detection of *P. falciparum* at 2000 parasites/µL was > 95% for all except one product. Only two of 24 products had a PDS below 75% against *P. vivax* at 200 parasites/µL, and all but one sample achieved > 97% at the higher density.

The HRP2 antigen was used to detect *P. falciparum* in all but five of the RDTs submitted to round 8. Of the 30 products that target HRP2, four contained HRP2 antigen only, in six products it was combined with Pf-LDH only (either on the same or separate test line), in nine products it was combined with pan-LDH or aldolase only, in nine products it was combined with Pv-LDH only, in one it was combined with Pvom-LDH and in one with both Pv-LDH and Pf-LDH. Of the products for use in areas where *pfhrp2/3* gene deletions are prevalent, one product detected *P. falciparum* with Pf-LDH alone, while nine other products combined a Pf-LDH target with another target. As in previous rounds of testing, RDTs with test lines for Pf-LDH for *P. falciparum* detection in phase 2 performed considerably less well than the HPR2-detecting test lines at 200 µL; the median PDS of products that detect HRP2 was 88.0%, and that of product test lines to detect Pf-LDH in the absence of HRP2 was 51.0%; however, this represents an improvement over past performance. Both pan-LDH-only products met WHO performance criteria for *P. falciparum* and *P. vivax*. Thus, after eight rounds of testing, the choice of well-performing non-HRP2-based *P. falciparum* tests remains limited, particularly combination tests that can discriminate between *P. falciparum* and non-*P. falciparum* infections.

The test performance of lots in round 8 varied slightly, with an average difference in positivity rates of 2.0 percentage points (range, 0–6.0%) and 2.4 percentage points (range, 0–14.3%) when tested against wild-type *P. falciparum* and *P. vivax* at 200 parasites/µL, respectively (Tables A3.1 and A4.1), a larger increase than in round 7. 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 8, all products

had at least one anomaly (Annex S2). Incomplete clearing and a red background were the most common anomalies, seen at least once in 100% and 94% of products, respectively. The next most common anomalies were a red background obscuring the test lines, incomplete migration and the strip being misplaced in the cassette, seen in 65%, 23% and 20% of products, respectively. In over half the products (24/35), < 10% of the tests had anomalies. Overall, a higher frequency of anomalies was seen in round 8 than in round 7.

All the RDTs evaluated in round 8 were in cassette format.

Only two of the 27 RDTs due for compulsory resubmission were submitted for retesting (Table S1). Both products (one combination and one *P. falciparum*-only RDT) met the WHO performance criteria. Both showed slightly fewer PDS percentage points than the previous time they were evaluated, in round 4, one by 2.8 and one by 1.9 percentage points for detection of clinical *P. falciparum* at 200 parasites/µL. The test that also targeted *P. vivax* showed an increase of 8.8 percentage points against low-density *P. vivax*. One product showed an increase in the false-positive rate of clean negatives of 2.1 percentage points, while the rate of the other product was 0.0% in both rounds.

Performance against the HRP2-negative panel was lower than that against the phase-2 *P. falciparum* panel for both HRP2 and Pf-LDH RDTs. The PDS of products that test for *P. falciparum* by HRP2 only ranged from 15% to 45%, while the range for products with Pf-LDH alone or in combination was 0–60%. Only the two pan-LDH-only products met WHO criteria in both panels. Several HRP2-RDTs detected HRP2-negative samples because of cross-reactivity with HRP3.

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 (*20*) 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, 98 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 reported, in conjunction with the WHO list of prequalified IVDs, should be used to make a short list of RDTs to be procured 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 malaria transmission and illness in the locality 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.

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 is available 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 (*20*). In addition to product performance, this online database allows filtering of results by RDT procedural characteristics, such as blood volume required, number of buffer drops and time to a result. This allows identification of products for which the procedures are similar, so that, when a product is to be replaced, another product with the same or a similar protocol can be selected. Use of similar products may reduce the need for user retraining and 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 configurations, such as single or multi-kits, 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 list the name and product code 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*

Box 3: WHO selection criteria for the procurement of RDTs

As of 1 January 2018, all RDTs for diagnosing *P. falciparum*–only malaria by detection of HRP2 are required to be prequalified for WHO procurement.[1]

All other products should have active applications with the WHO prequalification programme and be selected in line with the following criteria, based on the results of the assessment in the WHO malaria RDT product testing Programme:

(a) For the detection of *P. falciparum* in all transmission settings, the PDS should be at least 75% at 200 parasites/µL.

(b) For the detection of *P. vivax* in all transmission settings, the PDS should be at least 75% at 200 parasites/µL.

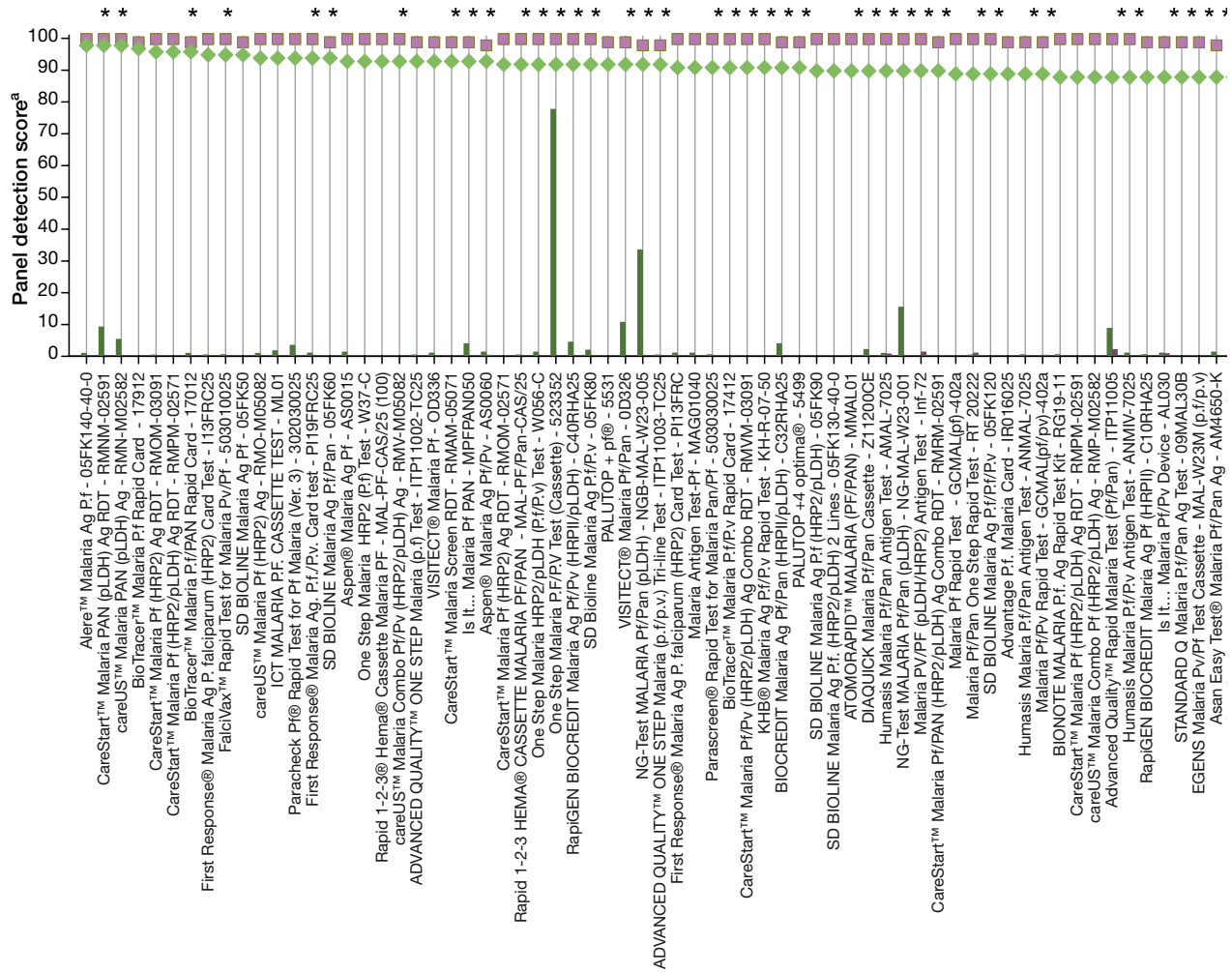
(c) The false positive rate should be less than 10%.

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

Only products that meet these performance criteria are recommended for procurement.

[1] http://www.who.int/malaria/news/2017/rdt-procurement-criteria/en, accessed 21 August 2018.

Figure S1: Malaria RDT performance in phase 2 of rounds 5–8 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.

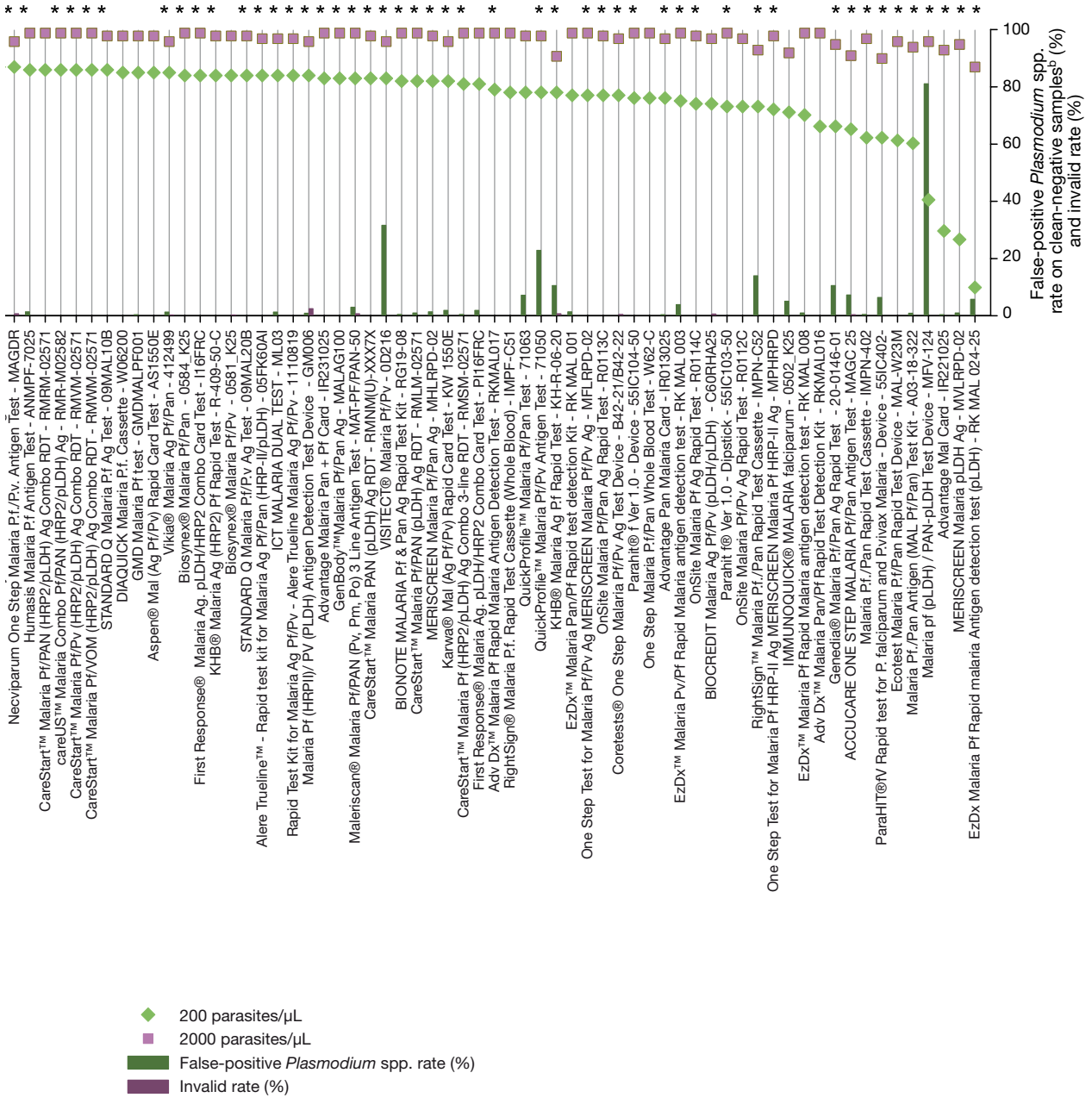
[b] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

* Indicates tests that also detect other non-*P. falciparum* parasites

procurement of malaria rapid diagnostic tests (21), published as a WHO information note, and *Good practices for selecting and procuring rapid diagnostic tests for malaria* (*22*). Guidance on implementation is provided in *Universal access to malaria diagnosis* (*23*).

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

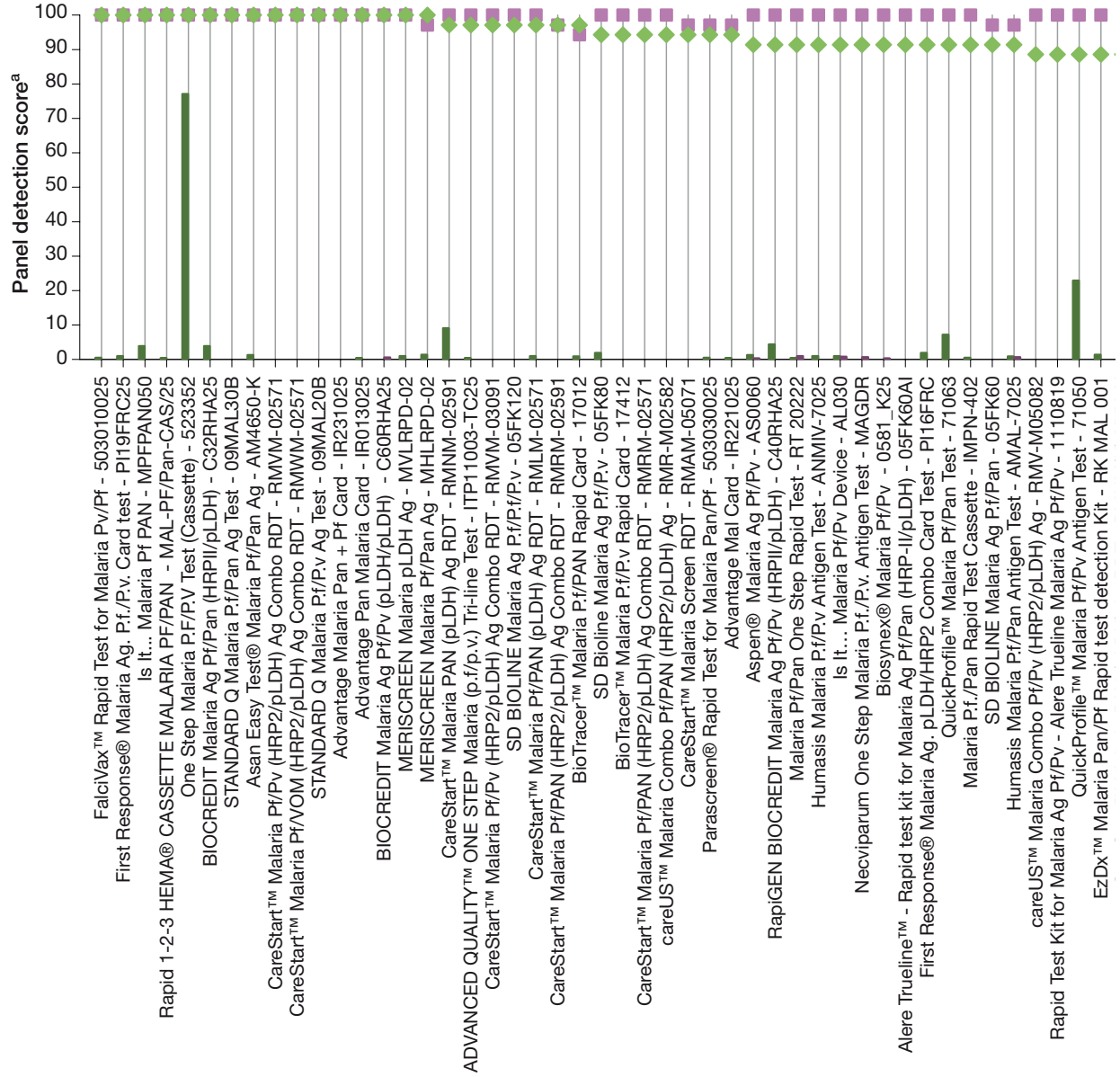
The data are used to set priorities for WHO prequalification dossier review and inspection. As per the new requirements announced in May 2016, manufacturers of products that met the WHO procurement criteria in previous rounds of



product testing were required to submit an application for WHO prequalification by 31 December 2016. Of the products evaluated in round 8, ten were withdrawn from the WHO prequalification process, one application was closed, and no applications were received for three products. Progress in the active applications for prequalification of IVDs can be followed at: *http://www.who.int/diagnostics_laboratory/180808_malaria.pdf?ua=1* (accessed 21 August 2018). WHO prequalified products are indicated in Table S2, and a complete list of WHO prequalified IVDs can be found at: *http://www.who.int/diagnostics_laboratory/evaluations/180806_prequalified_product_list.pdf?ua=1* (accessed 21 August 2018).

It is expected that, by the end of 2018, more manufacturers will have completed the prequalification process, and a requirement for WHO prequalification designation will be extended to malaria RDTs other than HRP2-detecting *P. falciparum*-only RDTs.

Figure S2: Malaria RDT performance in phase 2 of rounds 5–8 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.

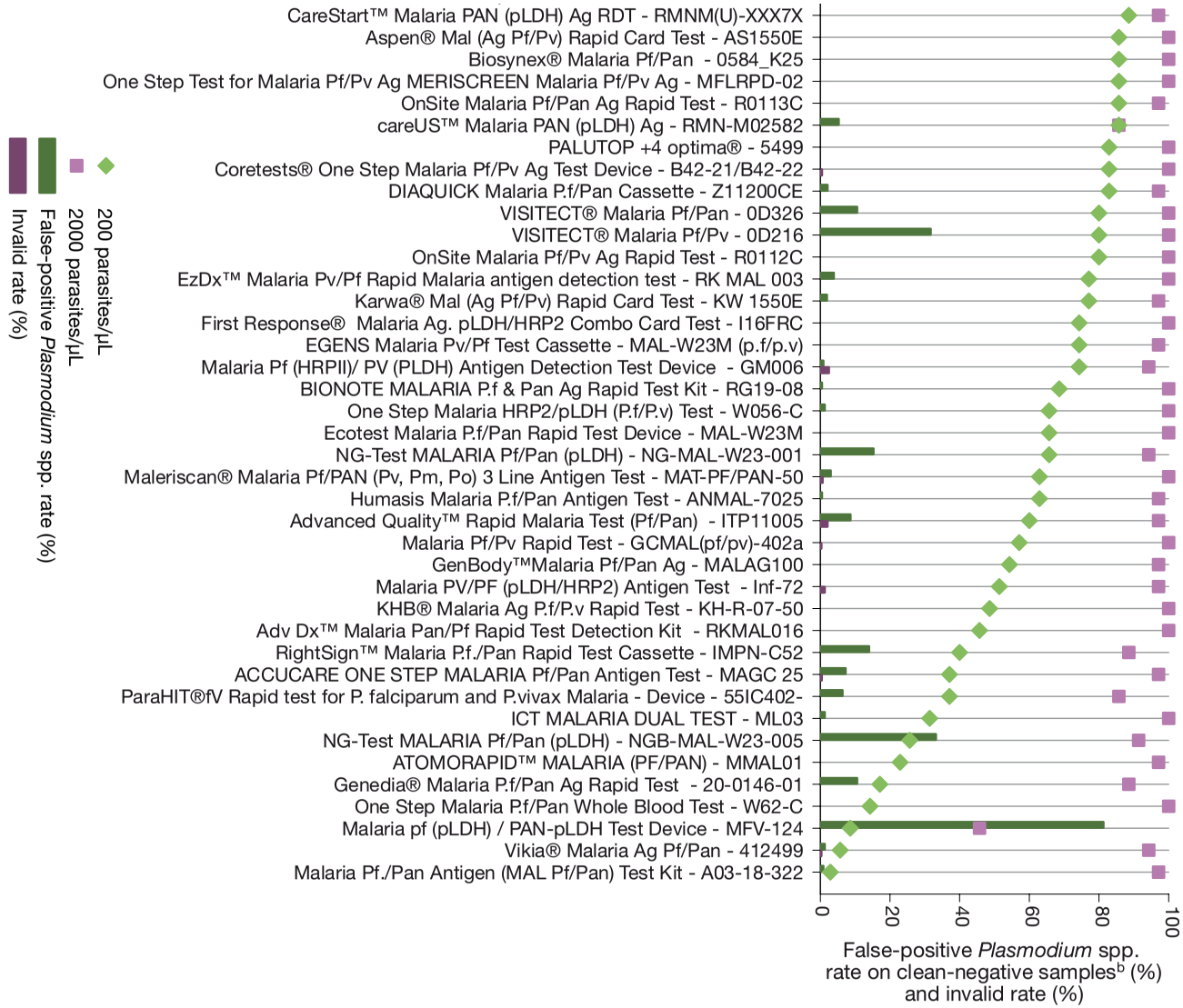
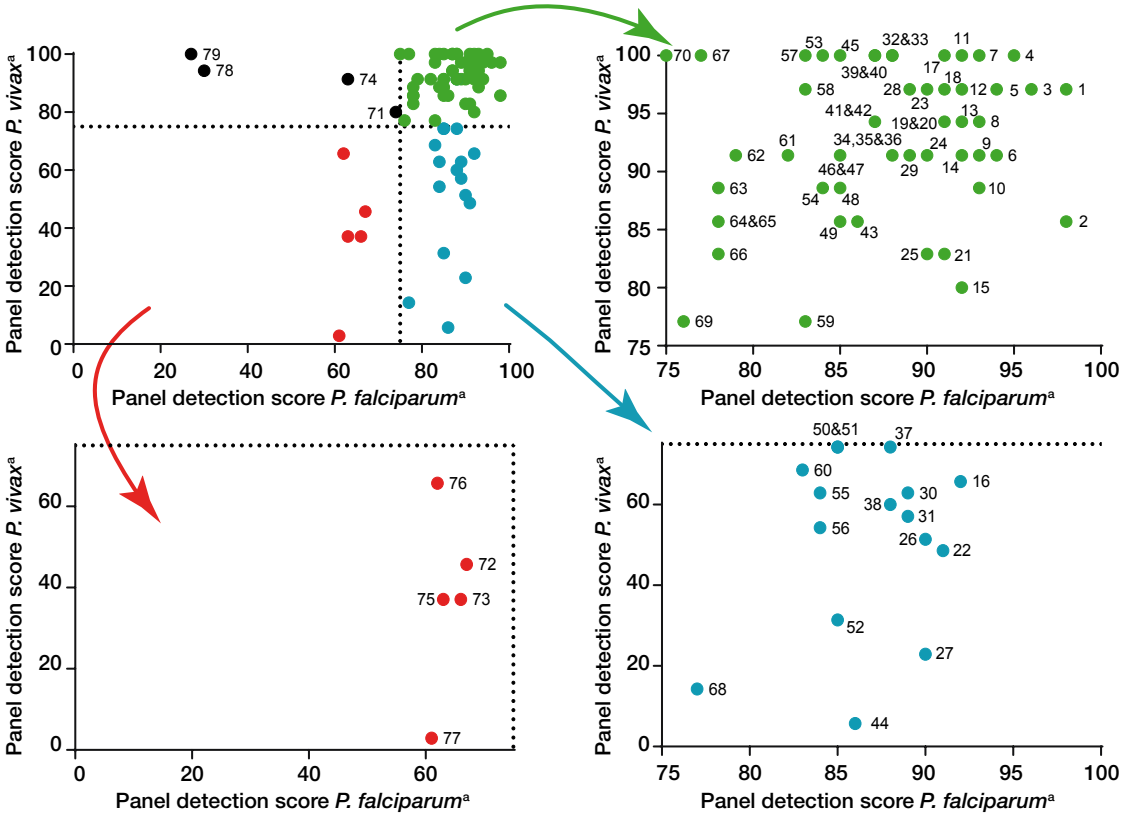

CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
Biosynex® Malaria Pf/Pan - 0584_K25
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
PALUTOP +4 optima® - 5499
Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
VISITECT® Malaria Pf/Pan - 0D326
VISITECT® Malaria Pf/Pv - 0D216
OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
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
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
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-
ICT MALARIA DUAL TEST - ML03
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
Vikia® Malaria Ag Pf/Pan - 412499
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)
200 parasites/µL
2000 parasites/µL
False-positive Plasmodium spp. rate (%)
Invalid rate (%)

Figure S3: Panel detection score of malaria combination RDTs meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 5–8 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low parasite density (200 parasites/µL)



1 CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM-02591
2 careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
3 BioTracer™ Malaria P.f/PAN Rapid Card - 17012
4 FalciVax™ Rapid Test for Malaria Pv/Pf j - 503010025
5 First Response® Malaria Ag. P.f./P.v. Card test j - PI19FRC25
6 SD BIOLINE Malaria Ag P.f/Pan - 05FK60
7 Is It... Malaria Pf PAN - MPFPAN050
8 CareStart™ Malaria Screen RDT - RMAM-05071
9 Aspen® Malaria Ag Pf/Pv - AS0060
10 careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag - RMV-M05082
11 Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN - MAL-PF/Pan-CAS/25
12 ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test - ITP11003-TC25
13 SD Bioline Malaria Ag P.f/P.v - 05FK80
14 RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH) - C40RHA25
15 VISITECT® Malaria Pf/Pan - 0D326
16 One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
17 BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) - C32RHA25
18 CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-03091
19 Parascreen® Rapid Test for Malaria Pan/Pf j - 503030025
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 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
24 Humasis Malaria P.f/Pan Antigen Test - AMAL-7025
25 DIAQUICK Malaria P.f/Pan Cassette - Z11200CE
26 Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
27 ATOMORAPID™ MALARIA (PF/PAN) - MMAL01
28 SD BIOLINE Malaria Ag P.f/P.f/P.v j , k - 05FK120
29 Malaria Pf/Pan One Step Rapid Test - RT 20222
30 Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
31 Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
32 Asan Easy Test® Malaria Pf/Pan Ag - AM4650-K
33 STANDARD Q Malaria P.f/Pan Ag Test - 09MAL30B
34 Is It… Malaria Pf/Pv Device - AL030
35 Humasis Malaria P.f/P.v Antigen Test - ANMIV-7025
36 Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
37 EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
38 Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
39 CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT j - RMVM-02571
40 CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT j - RMWM-02571
41 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT j - RMRM-02571
42 careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
43 Aspen® Mal (Ag Pf/Pv) Rapid Card Test j - AS1550E
44 Vikia® Malaria Ag Pf/Pan - 412499
45 STANDARD Q Malaria P.f/P.v Ag Test - 09MAL20B
46 Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
47 Biosynex® Malaria Pf/Pv - 0581_K25
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 ICT MALARIA DUAL TEST - ML03
53 Advantage Malaria Pan + Pf Card - IR231025
54 CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
55 Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
56 GenBody™Malaria Pf/Pan Ag - MALAG100
57 MERISCREEN Malaria Pf/Pan Ag j - MHLRPD-02
58 CareStart™ Malaria Pf/PAN (pLDH) Ag RDT j - RMLM-02571
59 Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
60 BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
61 First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - PI16FRC
62 QuickProfile™ Malaria Pf/Pan Test - 71063
63 EzDx™ Malaria Pan/Pf Rapid test detection Kit - RK MAL 001
64 OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
65 One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
66 Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
67 Advantage Pan Malaria Card - IR013025
68 One Step Malaria P.f/Pan Whole Blood Test - W62-C
69 EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
70 BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
71 OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
72 Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
73 ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
74 Malaria P.f./Pan Rapid Test Cassette j - IMPN-402
75 ParaHIT®fV Rapid test for *P. falciparum* and *P.vivax* Malaria - Device - 55IC402-50
76 Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
77 Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
78 Advantage Mal Card - IR221025
79 MERISCREEN Malaria pLDH Ag - MVLRPD-02

[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 1–8

Manufacturer	Product name	Product code*	Product resubmission Round	
			Voluntary	Compulsory
Access Blo, Inc.	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-05072[a]	2, 4, 7, 8	
	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	RMWM(U)-XXX7X[b]	2, 4	8
	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM(U)-XXX7X[c]	1, 8	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	RMRM(U)-XXX7X[d]	1, 8	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, 8	6
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071[g]	3, 8	7
	CareStart™ Malaria Screen RDT	RMAM-05071[h]	3	7
	CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	7, 8	
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.[i]	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	
Hangzhou AllTest Biotech Co. Ltd.	Malaria P.f./ Pan Rapid Test Cassette	IMPN-402	7, 8	
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]	30301025/302030025	1, 3, 4	8
	Paracheck® Pf Dipstick - Rapid test for *P. falciparum* Malaria (Ver.3)[n]	30302025/302040025	1, 3, 4	
	First Response® Malaria Ag Combo (pLDH/HRP2)[o]	I16FRC25	1, 2, 5	
Premier Medical Corporation Ltd.	First Response Malaria Ag *P. falciparum*(HRP2) Card Test	I13FRC25	1	5
	First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	6, 8	
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, 8	
	SD Bioline Malaria Ag P.f/P.v	05FK80	2	6
	SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	6, 8	
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, 8	
	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025; 503010025 (rd 6)	2, 4, 6, 8	

* The same RDT may be sold in a variety of product configurations e.g. single or multi-kits, the number of tests per box, with or without certain accessories and on these bases, assigned a series of distinct product codes. The reports list the exact name and product codes as provided by the manufacturer for testing. Procurers should contact the manufacturer for a list of product configurations prior to purchase.

[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

[i] 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] Product name (Ver.3) and product code (302030025 and 302040025) revisions were introduced after rounds 1 and 3, respectively.

[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 5–8 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 performance criteria
			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[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														
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	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 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) Ag RDT[j]	RMOM-02571	Access Bio Inc.	92.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.1	8	Yes[m]
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT[j, k]	RMSM-02571	Access Bio Inc.	82.0 (81/40)	NA	100.0 (99/95)	NA	NA	1.4	NA	2.9	0.5	0.0	8	Yes
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	8	Yes
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT[j]	RMPM-02571	Access Bio Inc.	96.0	NA	100.0	NA	NA	0.0	NA	1.4	0.0	0.0	8	Yes[m]
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	8	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 (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	10.0	NA	88.0	NA	NA	5.0	NA	12.9	5.8	0.0	8	No
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
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
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	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
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	7	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 Pf Malaria (Ver. 3)[j]	302030025	Orchid Biomedical Systems (Tulip Group)	94.0	NA	100.0	NA	NA	1.4	NA	4.3	3.4 (207)	0.1	8	Yes
Parahit f® Ver 1.0 - Dipstick	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	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 performance criteria
			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[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)[j, k]	05FK90	Standard Diagnostics Inc. (Alere)	90.0 (88/71)	NA	100.0 (99/98)	NA	NA	0.0	NA	0.0	0.0	0.1	8	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]
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	87.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	8	Yes
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	93.0	NA	99.0	NA	NA	0.0 (139)	NA	1.4	1.0	0.1	8	Yes
Pf and Pan														
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	66.0	37.1	92.0	97.1	0.3	0 (139)	0.0 (199)	0.0	7.3 (234)	0.4	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
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	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
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	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	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 (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	90.0	97.1	99.0	97.1	2.0	0.0	0.5	1.4	0.0	0.0	8	Yes
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT[j]	RMRM-02571	Access Bio Inc.	87.0	94.3	100.0	100.0	3.0	0.7	0.0	0.0	0.0	0.0	8	Yes[m]
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT[j]	RMLM-02571	Access Bio Inc.	83.0	97.1	100.0	100.0	2.0	0.0 (139)	0.0	0.0	1.0	0.1	8	Yes
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	7	Yes
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	87.0	94.3	100.0	100.0	3.0	0.7	0.0	0.0	0.0	0.0	8	Yes
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
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	62.0	65.7	97.0	100.0	0.5	0.7	2.0	0.0	0.0	0.0	8	No
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
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	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	0.0 (68)	1.0 (206)	0.8	6	Yes
Malaria P.f./Pan Rapid Test Cassette[j]	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	63.0	91.4	98.0	100.0	0.5	0.0	0.0	0.0	0.5	0.0	8	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 (398)	4.3	0.0 (199)	0.0	0.9	0.2	5	No
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	100.0	100.0	0.0 (398)	0.7 (138)	0.0 (199)	0.0 (69)	0.4 (232)	1.0	5	Yes
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	83.0	100.0	99.0	97.1	1.3	0.0	0.5	1.4	1.4	0.1	8	Yes

(continued)

Table S2: Malaria RDT phase 2 performance in rounds 5–8 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 performance criteria
			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[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]			
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	27.0	100.0	96.0	100.0	10.3	0.0	1.5	0.0	1.0	0.0	8	No
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	100.0	94.3	0.5 (399)	9.3	0.0	4.3	15.3	0.1	5	No
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
Parascreen® Rapid Test for Malaria Pan/Pf[j]	503030025	Zephyr Biomedicals	91.0	94.3	100.0	97.1	0.0	0.7	0.0	1.4	0.5	0.0	8	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]
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	88.0	100.0	99.0	100.0	0.0	0.0	0.5	0.0	0.0	0.0	8	Yes
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
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	92.0	80.0	99.0	100.0	0.5 (398)	0.7 (139)	0.5	0.0	10.6	0.2	8	No
Pf and Pv/Pvom														
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	7	Yes
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	86.0	85.7	99.0	100.0	1.0	0.0	1.0	0.0 (69)	0.0	0.1	8	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-02571	Access Bio Inc.	87.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	8	Yes[m]
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT[j]	RMWM-02571	Access Bio Inc.	87.0	100.0	100.0	100.0	3.0	0.0	0.5	0.0	0.0	0.0	8	Yes
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
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	88.0	74.3	99.0	97.1	1.8	0.0	0.0 (199)	1.4	0.0	0.1	8	No
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	100.0	100.0	1.3	1.4	0.0	1.4	3.9	0.0	6	Yes
FalciVax™ Rapid Test for Malaria Pv/Pf[j]	503010025	Zephyr Biomedicals	95.0	100.0	100.0	100.0	0.8	0.0	0.0	0.0	0.5	0.0	8	Yes
First Response® Malaria Ag. P.f./P.v. Card test[j]	PI19FRC25	Premier Medical Corporation Private Ltd.	94.0	100.0	100.0	100.0	0.8 (399)	0.7	0.5	0.0	1.0	0.1	8	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
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	83.0	77.1	97.0	97.1	0.3	0.0	0.0	1.4	1.9	0.0	8	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 (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 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
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	88.0	91.4	97.0	100.0	0.3 (399)	0.7 (139)	1.5	0.0	0.0 (201)	0.7	8	Yes
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	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

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 performance criteria
			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[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]			
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	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 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
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]
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	85.0	100.0	99.0	100.0	0.5	0.0	0.5	0.0	0.0	0.0	8	Yes
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	84.0	80.0	97.0	100.0	37.3	12.9	20.0	2.9	31.7	0.0	8	No
Pf, Pf and Pv														
SD BIOLINE Malaria Ag P.f/P.f/P.v[j, k]	05FK120	Standard Diagnostics Inc. (Alere)	89.0 (89/62)	97.1	100.0 (99/99)	100.0	0.0	0.0	0.0	0.0	0.0	0.0	8	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
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]
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	98.0	97.1	100.0	100.0	NA	NA	NA	NA	9.1	0.0	8	Yes
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	98.0	85.7	100.0	85.7	NA	NA	NA	NA	5.3	0.0	8	Yes

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; Round 8, 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; Round7, n=35; Round 8, 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 ; Round 8, 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 ; Round 8, 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 ; Round 8, 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 ; Round 8, 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 ; Round 8, n=208

[j] Product resubmission in round 8. Results from round 8 replace previous results. Refer to Table S1 for full history of product resubmissions (rounds 1-8).

[k] PDS presented in the table is based on a positive Pf test line (either HRP2 or Pf-LDH). The results in brackets are the PDS based alone on HRP2 and Pf-LDH 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; Round 8, n=1210

[m] Indicates a WHO prequalified product

[n] ARKRAY Healthcare Pvt. Ltd. was formerly Span Diagnostics Ltd.

[p] PDS presented in the table is based on one of the positive test lines (either Pan-LDH or Pv-LDH). For test line specific results refer to the tables and annexes in the full reports.

Performance measure	Recommended WHO performance 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 5–8 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															
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	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 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) Ag RDT [a]	RMOM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT [a, b]	RMSM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT [a]	RMPM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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 (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	70.0	56.7	33.3	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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
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
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	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
One Step Malaria HRP2 (P.f) Test	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 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 Pf Malaria (Ver. 3) [a]	302030025	Orchid Biomedical Systems (Tulip Group)	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
Parahit f® Ver 1.0 - Dipstick	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	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) [a, b]	05FK90	Standard Diagnostics Inc. (Alere)	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8

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															
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
Asan Easy Test® Malaria Pf/Pan Ag	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
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	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	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 (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	100.0	93.3	96.7	100.0	100.0	100.0	8
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT [a]	RMRM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	96.7	100.0	100.0	100.0	8
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT [a]	RMLM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	70.0	100.0	100.0	100.0	8
CareStart™ Malaria Screen RDT	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
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	83.3	100.0	100.0	100.0	8
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
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	100.0	100.0	100.0	100.0	100.0	100.0	26.7	0.0	6.7	100.0	100.0	100.0	8
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
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	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 P.f./Pan Rapid Test Cassette [a]	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	30.0	43.3	83.3	100.0	100.0	100.0	8
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 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
MERISCREEN Malaria Pf/Pan Ag [a]	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	96.7	100.0	100.0	100.0	8
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	63.3	73.3	93.3	90.0	100.0	100.0	53.3	76.7	96.7	90.0	100.0	100.0	8
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
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
Parascreen® Rapid Test for Malaria Pan/Pf [a]	503030025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	76.7	73.3	100.0	100.0	100.0	8

(continued)

Table S3: Malaria RDT rounds 5–8 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			
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
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	100.0	100.0	100.0	100.0	100.0	100.0	16.7	50.0	93.3	100.0	100.0	100.0	8
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
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	46.7	70.0	70.0	100.0	100.0	100.0	8
Pf and Pv/Pvom															
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test	ITP11003-TC25	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT [a]	RMWM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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
EGENS Malaria Pv/Pf Test Cassette	M A L - W 2 3 M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
FalciVax™ Rapid Test for Malaria Pv/Pf[a]	503010025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
First Response® Malaria Ag. P.f./P.v. Card test[a]	PI19FRC25	Premier Medical Corporation Private Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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 (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 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
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
One Step Malaria HRP2/pLDH (P.f/P.v) Test	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	ARKRAY Healthcare Pvt Ltd c	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	71050	Lumiquick Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
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
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
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
Pf, Pf and Pv															

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			
SD BIOLINE Malaria Ag P.f/P.f/P.v[a, b]	05FK120	Standard Diagnostics Inc. (Alere)	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
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
CareStart™ Malaria PAN (pLDH) Ag RDT	R M N M (U) - XXX7X	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	8
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	8

Product	Product code	Manufacturer	Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (Pf line)			Percent positive test results for *P. falciparum* (pan line)			Percent positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µL			2000 parasites/µL			200 parasites/µL			2000 parasites/µL			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Number of tests positive			Number of tests positive			Number of tests positive			Number of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - (Pf(HRP2) band)	RMSM-02571	Access Bio Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - (Pf(LDH) band)			0.0	0.0	0.0	80.0	100.0	20.0	NA	NA	NA	NA	NA	NA	8
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - (Pf(HRP2) band)	05FK90	Standard Diagnostics Inc. (Alere)	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - (Pf(LDH) band)			100.0	100.0	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
SD BIOLINE Malaria Ag P.f/P.f/P.v - (Pf(HRP2) band)	05FK120	Standard Diagnostics Inc. (Alere)	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8
SD BIOLINE Malaria Ag P.f/P.f/P.v - (Pf(LDH) band)			100.0	93.3	96.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	8

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 performance 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-LDH). Results based on stability of individual test lines is presented in the table below.

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

Table S4: Products evaluated during rounds 1–8 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
	ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402
	ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402
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
Artron Laboratories Inc.	TrustyTM Malaria Antigen P.f. test	A03-01-322
	TrustyTM Malaria Antigen P.f./p.v. test	A03-12-322
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
	AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F
	AZOG hCG Malaria Detection Test Device	MPT-124
Bhat Bio-Tech India (P) Ltd	Maleriscan® Malaria Pf/Pv	MAT-50
	Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10
	NanoSign Malaria Pf/Pv Ag	RMAD10
	NanoSign Malaria pf/pan Ag 3.0	RMAP10
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
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (Cassette)	522352
Core Diagnostics	Core™ Malaria Pf	MAL-190020
	Core™ Malaria Pan Pf	MAL-190024
	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
Formosa Biomedical Technology Corp.	MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K
Genomix Molecular Diagnostics Pvt.Ltd.	Malaria Pf/ PAN	GM004
	Malaria Pf/Pv	GM002
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
	HiSens Malaria Ag P.f/P.v Combo Card	HR3123
	HiSens Malaria Ag P.f/VOM Combo Card	HR3323
Hema Diagnostic Systems, LLC	RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)
Human GmbH	Hexagon Malaria	58051
	Hexagon Malaria Combi	58024
Humasis, Co., Ltd.	Humasis Malaria P.f/P.v Antigen Test	AMFV-7025
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
Meril Diagnostics Private Ltd.	Meriscreen Malaria Pf/Pan Ag	MHLRPD-01
Orchid Biomedical Systems	Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)	302040025
Orgenics Ltd. (Inverness Innovations)	Clearview® Malaria pLDH	70884025

Table S4 *(continued)*

Manufacturer	Product name	Product code
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/ARKRAY Healthcare Pvt. Ltd.	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
	ParaHIT - Total Ver. 1.0 (Device)	55IC204-10
	ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10
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
	FirstSign™ Malaria Pf	2100CB-25
	FirstSign™ ParaView (Pan+Pf)	2101CB-25
United Biotech, Inc.	Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3
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

[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 2016, there were an estimated 216 million cases (with an uncertainty range of 196 million to 263 million) and an estimated 445 000 deaths (with an uncertainty range of 402 000 to 486 000). Approximately 91% 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 2014 and 2016 suggest that approximately 70% of suspected cases of malaria in children 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 had not previously been a requirement for WHO procurement; however, as of 1 January 2018, HRP2-based *P. falciparum*-only products must meet WHO prequalification requirements to be eligible for WHO procurement, and this requirement is likely to be extended to other malaria RDT types by the end of 2018.

This report provides the results of round 8 of product testing, performed at the CDC during 2016–2018, with data on the performance of 35 products. This round adds to the evaluations of rounds 1–7 (*3*–*9*), which should be considered as a single evaluation, except for the results for products tested in previous rounds that were resubmitted for testing, which 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. Notably, round 8 marks the first time *pfhrp2/3*-deleted parasites have been included in the assessment, in response to the emergence of reports of *pfhrp2/3* deletions in *P. falciparum* populations in several countries in Africa, Asia and South America. Thus, this report provides new data and extends the data from previous rounds, thereby increasing 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 five years, as a result of the compulsory resubmission policy. This policy will, however, be discontinued to align with WHO prequalification procedures.

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; in round 8, manufacturers were also required to submit an application to the WHO IVD prequalification programme. The 35 products from 17 manufacturers were evaluated with prepared blood panels of cultured *P. falciparum* parasites, and those that passed phase 1 were evaluated with patient-derived wild-type *P. falciparum* and *P. vivax* parasites and a parasite-negative panel. All products were also tested against a panel of HRP2-negative *P. falciparum* samples. Observed anomalies were recorded. Thermal stability was assessed after two months of storage at elevated temperature and humidity, and a rudimentary assessment of ease of use was recorded. As in previous rounds, RDTs are grouped in the tables and figures into those designed to detect *P. falciparum* only, various combination tests and those that have a line only for pan-specific (or *P. vivax*-specific) malaria. Manufacturers submitted two lots of each product for evaluation. The 14 products that had been tested in previous rounds comprised two compulsory resubmissions and 12 voluntary resubmissions (Tables 1a and 1b).

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). In response to the recent emergence in Africa, Asia and South America of *P. falciparum* populations with *hrp2* and *hrp3* gene deletions that cause "false"-negative RDT results, a panel of clinical and cultured *P. falciparum* samples with *hrp2* deletions, with or without *hrp3* deletions, was assembled to assess performance of round 8 products.

WHO product testing constitutes the laboratory evaluation component of the WHO prequalification process for malaria RDTs (*24*), which also includes a standardized dossier review and a manufacturing site inspection to ensure safety, quality and performance comprehensively. WHO prequalification of IVD, 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 is required for HRP2-based *P. falciparum*-only malaria RDTs to be eligible for procurement as of 1 January 2018. This requirement is expected to be extended to other categories of malaria RDTs by the end of 2018. Compulsory resubmission will no longer be required to align with WHO prequalification procedures for other products in the portfolio, such as HIV RDTs. Tables S1 and S4 indicate the frequency and nature of product resubmissions and removals from summary listings between rounds 1 and 8.

2.3 Results of the evaluation

The results (summarized in Tables 4 and 5 and Figs 9-15) 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 (*10*), and a higher parasite density (2000 parasites/µL).

For the purposes of this report, the main measure of performance is the PDS, the percentage of malaria samples in a panel that give a positive result in two RDTs per lot at the lower parasite density and a single RDT per lot at the higher parasite density. Thus, it is not a measure of clinical sensitivity or of the positivity rate against the panel but rather a combined measure of positivity rate and inter-test and inter-lot consistency. As in previous rounds of product testing, the PDS of products varied. 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. In round 8, the proportion of tests that achieved a PDS ≥ 75% at a density of 200 parasites/µL was slightly higher than in round 7 for *P. falciparum* (88.2%) and substantially higher for *P. vivax* (91.7%). Although the performance of the products varied at low parasite density (200 parasites/µL) in round 8, with four of 34 products having a PDS < 75%, the rate of detection of *P. falciparum* at 2000 parasites/µL was > 95% for all except one product. Only two of 24 products had a PDS < 75% against *P. vivax* at 200 parasites/µL, and all but one product achieved > 97% at the higher density.

The basis for *P. falciparum* detection by combination RDTs, particularly in samples with low parasite density, is usually 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-LDH (or Pf-LDH) combination products in the field, it is important to remember that the presence of a positive HRP2 band combined with a negative 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 8, the results for two products submitted for compulsory retesting showed a slight decrease in PDS as compared with the previous evaluation round, one by 2.8 percentage points and one by 1.9 percentage points for detection of clinical *P. falciparum* at 200 parasites/µL. Only one of the tests also targeted *P. vivax*, which showed an increase of 8.8 percentage points at 200 parasites/µL. One product showed an increase in the false-positive rate of clean negatives by 2.1 percentage points, while the other product had 0.0% PDS in both rounds.

Of the voluntary resubmissions, 67% (8/12) and 88% (7/8) of products showed the same or better detection of *P. falciparum* and of *P. vivax* at 200 parasites/µL, respectively. Specifically, the mean change in PDS was +2.9 percentage points (range, −6 to +15; n = 12) in tests for *P. falciparum* and +18.6 percentage points (range, −2.8 to +97.1; n = 8) for *P. vivax*. The mean change in the false-positive rate on clean negatives was -0.1 percentage points (range, -0.9 to + 0.9; n = 12), while 42% (5/12) had a better false-positive rate.

In combination tests, no significant correlation was found between the changes in *P. falciparum* and *P. vivax* detection rates ($p = 0.686$), suggesting that the changes in the detection of the two parasite species were independent.

In round 8, two of the products had very high false-positive rates of over 10% when tested against clean negatives. This is an improvement over the high rates observed in rounds 4 and 5 but worse than in round 7. In contrast, slightly fewer products reacted against blood samples containing specific immunological abnormalities and against samples containing non-*Plasmodium* infectious agents (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 8 (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 two months' storage at 45°C and 75% humidity; heat stability was higher at higher parasite density. One product showed decreased performance but had performed relatively poorly at baseline, with 70% positivity at baseline, 57% at 35°C and 33% at 45°C. For many products, pan-LDH performance at baseline and after heat stress for detection of the low-density *P. falciparum* isolate was poor, and the effects of heat were unpredicatble, some products showing improvement after heat stress, making it difficult to assess true stability. Products were also assessed for heat stability against a wild-type *P. vivax* sample. While most of the products performed

well, with high positivity rates after two months' storage at 45°C and 75% humidity, others showed some decrease in performance after storage, with little difference between pan-LDH and Pv-LDH in test line stability.

The frequencies of anomalies that can interfere with test interpretation were recorded. In round 8, all 35 products had at least one anomaly, with at least one anomaly in > 5% of tests in 54% (19/35) of products (Annex S2, Table 8, Fig. 30). Incomplete clearing and red background (not obscuring test lines) were the most common anomalies, seen in 100% and 94% of products, respectively. A red background obscuring the test lines, the strip being misplaced in the cassette and incomplete migration were the next most common anomalies, seen in 66%, 26% and 23% of products, respectively. Anomalies were seen more frequently than in round 7.

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 8 a new panel of HRP2-negative *P. falciparum* was introduced. The performance of both HRP2- and Pf-LDH-based RDTs was lower against the HRP2-negative panel than against the phase 2 *P. falciparum* panel. Only the two pan-LDH-only products met WHO criteria in both panels. Several HRP2 RDTs detected HRP2-negative samples because of cross-reactivity with HRP3.

The clinical sensitivity of an RDT, i.e. the proportion of known cases of 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 comparison of the performance of RDTs reported here indicates 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. The first set of comparative results for RDTs against *pfhrp2/3*-deleted clinical and cultured samples confirms that use of HRP2 and HRP2-pan-LDH RDTs will lead to either misdiagnoses or misclassification of malaria infections in areas where non-expression of HRP2 is present. HRP3 cross-reactivity may reduce the impact of negative and/or misclassified diagnoses but the extent will vary by brand of RDT and antigen concentration. Furthermore, for reasons not yet entirely understood, in round 8 most Pf-LDH based RDTs performed less well at detecting non HRP2/3 expressing *P. falciparum* samples than HRP2-expressing samples in Phase 2. A larger sample of geographically diverse *pfhrp2/3* deleted samples is needed to shed light on reasons for this discrepancy. Fortunately, pan-LDH tests evaluated in round 8 did peform comparably well on both the phase 2 wild-type *P. falciparum* panel and the HRP2-negative panel.

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 account 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* (*21*, published as a WHO information note in 2017, and guidance on implementation in *Universal access to malaria diagnosis* (*23*)).

3. Background

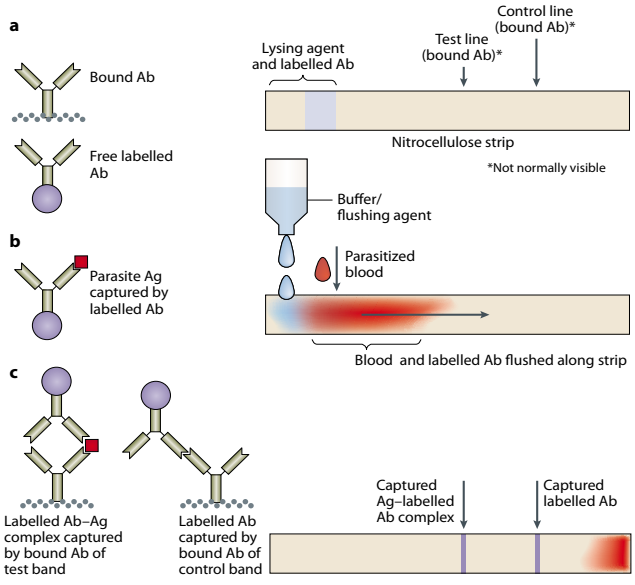
During the past decade, new opportunities for the control of malaria have emerged, including use of long-lasting insecticidal nets, indoor residual spraying of insecticides and artemisinin-based combination therapy. These have been shown to reduce the burden of malaria infection in countries where they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

Despite WHO's recommendation for a parasitologically confirmed diagnosis of malaria infection before treatment in all cases (*2*), diagnoses are still often made on clinical grounds (*10*); however, in 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 lack of 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 two main formats – cassette or dipstick – and contain antibodies bound to specific antigens, such as HRP2 specific to *P. falciparum*, pan-specific and species-specific LDH 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 (*25–33*). 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, with 312 million being sold in 2016. Since 2013, there has been a global decline, due to decreasing sales in Asia, although sales in Africa have risen every year since 2008, with 269 million RDTs delivered to Africa in 2016 (*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. The programme has also constituted the independent laboratory evaluation component of the WHO IVD prequalification process, in which an increasing number of products have achieved prequalification. Between 2003 and mid-2012, the programme was managed by WHO and TDR in partnership

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.

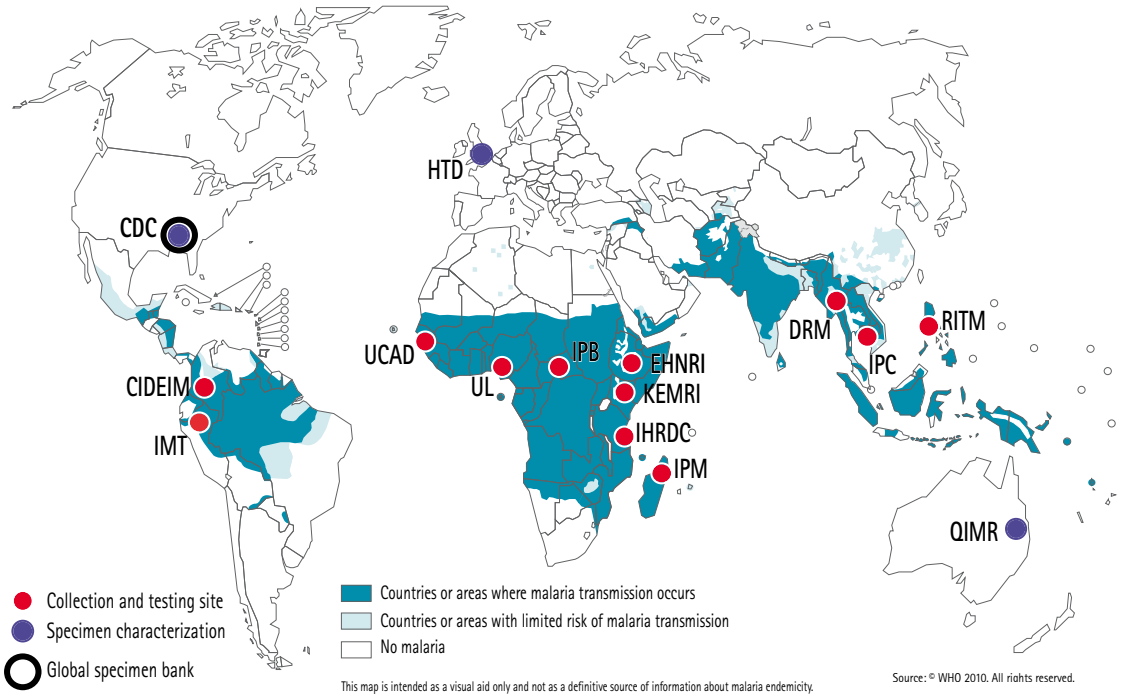
(b) Blood and buffer, which have been placed on the strip or in the well, are mixed with the labelled antibody and are drawn up the strip across the lines of bound antibody.

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

with FIND. After TDR withdrew its involvement in 2012, the WHO Global Malaria Programme assumed a coordinating role, and, in 2018, the WHO IVD prequalification programme took over this role. Between 2006 and 2018, a steering committee oversaw the development of and modifications to standard operating procedures (*34, 35*). A network of 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 seven rounds of product testing have been released annually since 2009 (*3–9*). This eighth report adds data on the performance of 21 new products and updated data on 14 resubmitted RDTs. Testing for round 8 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), with the addition of a new panel of HRP2-negative samples. Most panel samples for phase-1 and -2 testing were retained from previous rounds: 9 of 100 *P. falciparum*, 5 of 35 *P. vivax* and 19 of 100 negative samples were replaced (new) in round 8, and all samples in the HRP2-negative panel were new.

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



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

4. Objective

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

5. Materials and methods

5.1 Test selection

On 13 October 2016, 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 8 and the conditions for participation in the evaluation programme.[1] Manufacturers of products that had not been retested since round 4 were informed they must resubmit those 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

[1] http://www.who.int/malaria/news/2016/rdt-call-for-testing-round8/en/ (accessed 22 August 2018).

Table 1a: Manufacturers and products accepted into round 8 of WHO malaria RDT product testing programme

Manufacturer	Product name	Product code[a]	Target antigen(s)
Access Bio, Inc.	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	HRP2
	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Pan-LDH, HRP2
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT[c]	RMPM-02571	Pf-LDH/ HRP2
	CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT[b]	RMWM-02571	Pvom-LDH, HRP2
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT[c]	RMLM-02571	Pan-LDH, Pf-LDH
	CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT[c]	RMSM-02571	Pf-LDH, HRP2
	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT[c]	RMVM-02571	Pv-LDH, HRP2
Access Bio Ethiopia	CareStart™Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Pan-LDH, HRP2
	CareStart™Malaria PAN (pLDH) Ag RDT	RMNM-02591	Pan-LDH
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Pf-LDH/HRP2
Advy Chemical Pvt. Ltd.	EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Pf-LDH
	EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II)	RK MAL 025-25	Pf-LDH, HRP2
ASPEN LABORATORIES PVT.LTD	Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Pv-LDH, HRP2
Assure Tech (Hangzhou)	Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Pan-LDH-HRP2
Hangzhou AllTest Biotech Co. Ltd.	Malaria P.f./ Pan Rapid Test Cassette[c]	IMPN-402	pan-aldolase, HRP2
Karwa Enterprises pvt ltd	Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Pv-LDH, HRP2
Meril Diagnostics Pvt Ltd.	MERISCREEN Malaria pLDH Ag	MVLRPD-02	Pan-LDH, Pf-LDH
	MERISCREEN Malaria Pf / Pan Ag	MHLRPD-02	Pan-LDH, HRP2
Nantong Egens Biotechnology Co., Ltd.	EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Pv-LDH, HRP2
Nectar Lifesciences Limited	Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Pv-LDH, HRP2
Omega Diagnostics Ltd.	VISITECT® Malaria Pf/Pan	0D326	Pan-LDH, HRP2
	VISITECT® Malaria Pf/Pv	0D216	Pv-LDH, HRP2
	VISITECT® Malaria Pf	0D336	HRP2
Orchid Biomedical Systems (Tulip Group)	Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)[b]	302030025	HRP2
Premier Medical Corporation Private Ltd.	First Response® Malaria Ag. P.f./P.v. Card test[c]	PI19FRC25	Pv-LDH, HRP2
SD Biosensor	STANDARD Q Malaria P.f Ag Test	09MAL10B	HRP2
	STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	Pan-LDH, HRP2
	STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	Pv-LDH, HRP2
Standard Diagnostics Inc. (Alere)	SD BIOLINE Malaria Ag P.f/P.f/P.v[c]	05FK120	Pf-LDH, Pv-LDH, HRP2
	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)[c]	05FK90	Pf-LDH, HRP2
WELLS BIO, INC	careUSTM Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	Pan-LDH, HRP2
	careUSTM Malaria PAN (pLDH) Ag	RMN-M02582	Pan-LDH
	careUSTM Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	Pf-LDH/HRP2
Zephyr Biomedicals	FalciVax™ Rapid Test for Malaria Pv/Pf[c]	503010025	Pv-LDH, HRP2
	Parascreen® Rapid Test for Malaria Pan/Pf[c]	503030025	Pan-LDH, HRP2

LDH, lactate dehydrogrenase HRP2, histidine rich protein 2 Pv, *P. vivax* Pf, *P. falciparum* Pan, *Plasmodium* spp.

[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 8.

[c] Indicates products which have previously been submitted and were voluntarily resubmitted in round 8.

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), compliance with the product definition, deadlines for document submission and payment of fees. Additionally, for the first time, the expression of interest required submission of a WHO *prequalification pre-submission form*.[1]

Twenty-six manufacturers, proposing 67 products, responded to the call; however, only 35 products from 17 manufacturers were submitted by the deadline and were included in the evaluation (Table 1a). Product codes and verification with manufacturers showed that 14 of the 35 products (40%) had been submitted previously to one or more rounds, including two (6%) scheduled for compulsory resubmission (Table 1b). Of the 35 products, 34 met the minimum performance requirements in the initial evaluation against the *P. falciparum* culture-derived panel (phase 1) and were therefore evaluated fully in phase 2.

Of the 34 products that were fully evaluated, ten are designed to detect *P. falciparum* alone, 11 to detect and differentiate *P. falciparum* from non-*P. falciparum* malaria, ten to detect and differentiate *P. falciparum* from *P. vivax*, one to detect and differentiate between *P. falciparum* and *P. vivax, P. ovale and P. malariae*, and two to detect *Plasmodium* genus. Of these products, nine detect Pf-LDH. Three products had separate Pf-LDH and HRP2 detecting lines, and three combined Pf-LDH with HRP2 on the same line. Annexes 1 and 2 give a comprehensive overview of the product characteristics.

[1] *http://www.who.int/diagnostics_laboratory/evaluations/Application/en/*. (accessed 17 September 2018).

Table 1b: Products due for compulsory resubmission in round 8

Manufacturer	Product name	Product Code	Participation in round 8[a]
ABON Biopharm (Hangzhou) Co. Ltd	ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	No
	ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	No
Access Bio, Inc.	CareStart™ Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171[b]	Yes
ARKRAY Healthcare Pvt. Ltd.	ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	No
	ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	No
Artron Laboratories Inc.	TrustyTM Malaria Antigen P.f./p.v. test	A03-12-322	No
	TrustyTM Malaria Antigen P.f. test	A03-01-322	No
AZOG, INC.	AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device	MFV-124F	No
	AZOG hCG Malaria Detection Test Device	MPT-124	No
Bhat Bio-Tech India (Pte.) Ltd.	Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	No
Bioland Ltd.	NanoSign Malaria pf/pan Ag 3.0	RMAP10	No
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria P.F Test (Cassette)	522352	No
Core Diagnostics Ltd.	Core™ Malaria Pan Pf	MAL-190024	No
Formosa Biomedical Technology Corp.	MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	No
Genomix Molecular Diagnostics Pvt.Ltd.	Malaria Pf/ PAN	GM004	No
	Malaria Pf/Pv	GM002	No
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Combo Card	HR3123	No
	HiSens Malaria Ag P.f/VOM Combo Card	HR3323	No
Hema Diagnostic Systems, LLC	RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	No
Humasis, Co., Ltd.	Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	No
Orchid Biomedical Systems	Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver.3)	302030025	Yes
	Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)	302040025	No
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag Pf/ Pan	05FK66	No
Unimed International Inc.	FirstSign™ ParaView (Pan+Pf)	2101CB-25	No
	FirstSign™ Malaria Pf	2100CB-25	No
United Biotech, Inc.	Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	No
	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	No

[a] The results of the first testing of the products in this list that were not retested in round 8 have been removed from tables S2 and S3 and figs S1 and S2 and are listed in table S4.

[b] Resubmitted to round 8 with new product code RMWM-02571

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 (*34*). In brief, RDTs from each of two lots of each product were evaluated against panels of parasite-positive, parasite-negative and HRP2-negative cryopreserved blood samples. Both lots were also tested for heat (thermal) stability after two 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.

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 four panels:

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

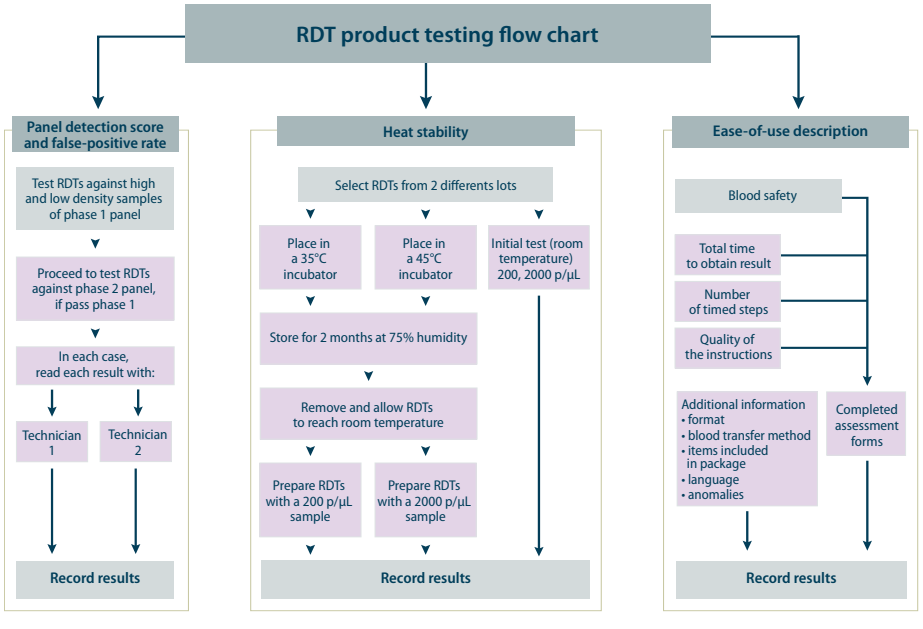
For the HRP2-negative panel, wild-type *P. falciparum* species from naturally infected humans was diluted with parasite-negative samples to low density (200 parasites/µL), and all samples were prepared from isolates with *pfhrp2* and *pfhrp3* gene deletion, so they do not express the HRP2 or HRP3 proteins. In addition, dilution series with antigen concentrations comparable to 200 parasites/µL were prepared from three HRP2-negative cultured isolates, two of which did express HRP3 and one of which did not express HRP3.

An overview of sample collection and characterization is given in the methods manuals prepared for this purpose (*34, 35*). Characterization results for each round are available in the reports of previous rounds (*3–9*) and in Annex S1. 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;
- the absence of malaria parasites by nested PCR and confirmatory testing for other diseases in the case of parasite-negative samples; and
- the presence or absence of *pfhrp2* and *pfhrp3* genes by PCR according to methods published elsewhere *(12)*.

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 cumulated evidence indicates that HRP2 variation has no significant effect on RDT sensitivity (*36*). The geographical origin of all samples was recorded.

Figure 3: Overview of malaria RDT product testing



Panel composition

P. falciparum-cultured parasites panel (phase 1)

Culture-adapted strains of *P. falciparum* were selected from various geographical locations, including 13 strains with type B HRP2 sequence, five with type A and two with type C (*36*). All specimens were derived from the CDC culture bank and diluted in O-positive blood from donors in the USA (*34*).

Wild-type parasite panel (phase 2)

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 (*35*). 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 99 for aldolase, 35 *P. vivax* samples for pLDH and 35 *P. vivax* samples for aldolase. This panel is closely comparable to those used in previous rounds (Annex S1).

Negative blood sample panel (phases 1 and 2)

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.

HRP2-negative blood sample panel

- *Wild-type strains*: Seven *P. falciparum*-positive, PCR-confirmed *pfhrp2*- and *pfhrp3*-negative wild-type (clinical) panels from Peru were diluted to 200 parasites/µL. All had an HRP2 concentration ≤ 0.2 ng/mL.
- *Cultured strains*: Three isolated cultured *P. falciparum* strains were selected: 3BD5, which is *pfhrp2*- and *pfhrp3*-negative, and Dd2 and D10, which are *pfhrp2*-negative but *pfhrp3*-positive. Eleven dilutions of each culture isolate were prepared to match the range of antigen concentrations found in the phase 2 wild-type *P. falciparum* 200 parasites/µL panel (*35*).
- *Deletion characteristics*: 22 samples had dual deletions (*pfhrp2*- and *pfhrp3*-negative), and 18 were *pfhrp2*-negative and *pfhrp3*-positive. The concentrations of antigens (HRP2, pLDH, aldolase) were determined by quantititive ELISA (Table 3b).

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.

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

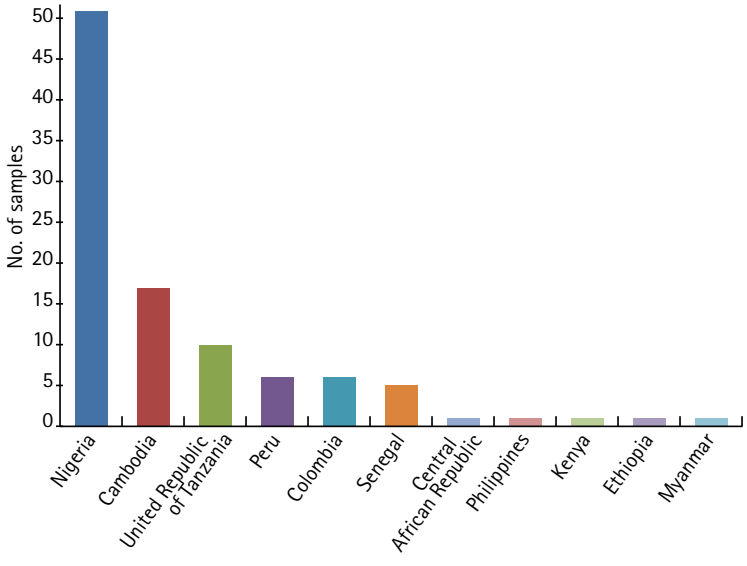


Figure 4b: Origin of phase 2 *P. vivax* wild-type (clinical) samples (n=35)

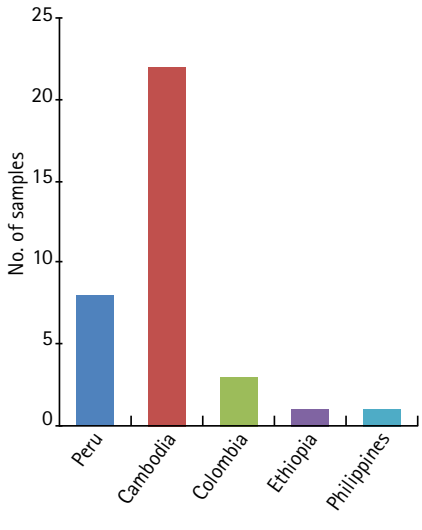


Table 2: Characteristics of *Plasmodium* spp. negative samples

Nature of negative sample[a]	No.
Clean-negative[b]	52
Anti-nuclear antibody positive (sera)	14
Anti-mouse antibody positive (plasma)	2
Rheumatoid factor positive (whole blood and sera)	6
Rapid plasma reagin positive (sera)	5
Chagas' disease antibody positive (plasma)	4
Dengue antibody positive (whole blood sera)	6
Leishmaniasis antibody positive (sera)	1
Schistosomiasis antibody positive (whole blood and sera)	10

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

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

5.5 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 (1, 2, HRP2-negative panel)

The evaluation is typically divided into two phases; however, in round 8, there was an additional third phase to assess RDT performance against an HRP2-negative *P. falciparum* panel.

Each lot of RDTs was evaluated independently. Lots 1 and 2 of each product were tested alternately against defined sample sets. Thus, 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.

5.6.1 Phase 1

A screening step is used to allow selection of RDTs that meet the minimum 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.

5.6.2 Phase 2

Products from two lots are evaluated against a panel of diluted clinical blood samples containing wild-type parasites, against a parasite-negative panel, for heat (thermal) stability and for ease of use. As there were fewer aliquots, fewer replicate RDTs were tested.

- Performance assessment: The mixed parasite-positive and parasite-negative panel comprised 100 *P. falciparum*, 35 *P. vivax* at two parasite densities (200 and 2000 parasites/µL) and 100 parasite-negative samples.
- Evaluation of the heat stability of *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 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. All were tested at baseline and

Table 3a: Malaria antigen concentrations (ng/mL) in round 8 wild-type, low parasite density (200 parasites/µL) samples

	pLDH		HRP2	Aldolase	
	P. falciparum (n=98)	*P. vivax (n=35)*	*P. falciparum (n=99)*	*P. falciparum (n=99)*	*P. vivax (n=35)*
Mean	16.13	15.93	11.76	1.37	7.88
Median	13.59	15.79	6.76	1.19	7.62
Maximum	53.53	37.94	62.48	9.08	15.08
Minimum	0.19	2.92	0.67	0.00	1.51
Standard deviation	11.49	9.89	12.96	1.32	3.79

pLDH, parasite lactate dehydrogrenase; HRP2, histidine rich protein 2

Table 3b: Malaria antigen concentrations (ng/mL) in round 8 HRP2-negative panel

	pLDH n=40	HRP2 n=40	Aldolase n=39
Mean	13.75	0.27	3.53
Median	9.85	0.11	2.70
Maximum	58.00	1.70	10.30
Minimum	2.50	0.00	0.20
Standard deviation	11.59	0.39	2.36

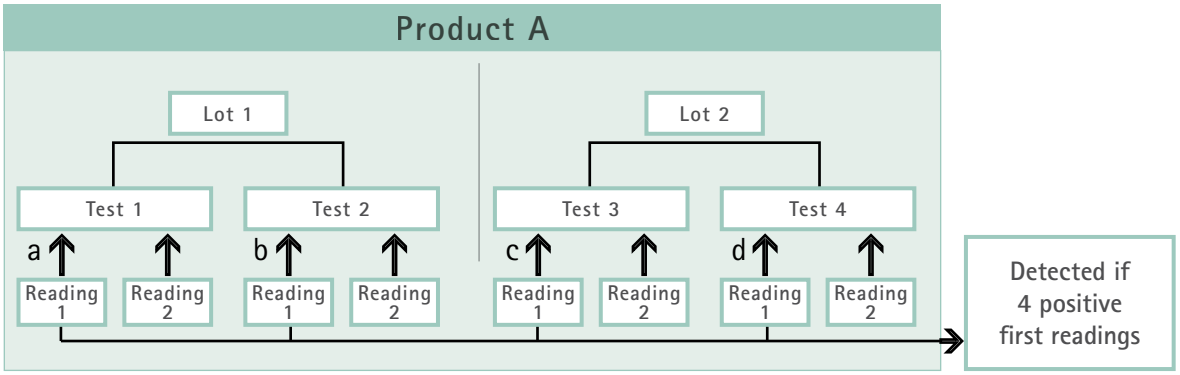
after being maintained for 60 days at room temperature (21–24°C), 35°C and 45°C, at 75% humidity.

Evaluation of the heat stability of *P. vivax*-detecting products: Four RDTs from each of two lots were tested against a single wild-type *P. vivax* sample (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 being 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 (*35*).
- RDT anomalies: During testing, technicians regularly reported on the RDT anomalies listed below (not all of which were observed in round 8) 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,

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.

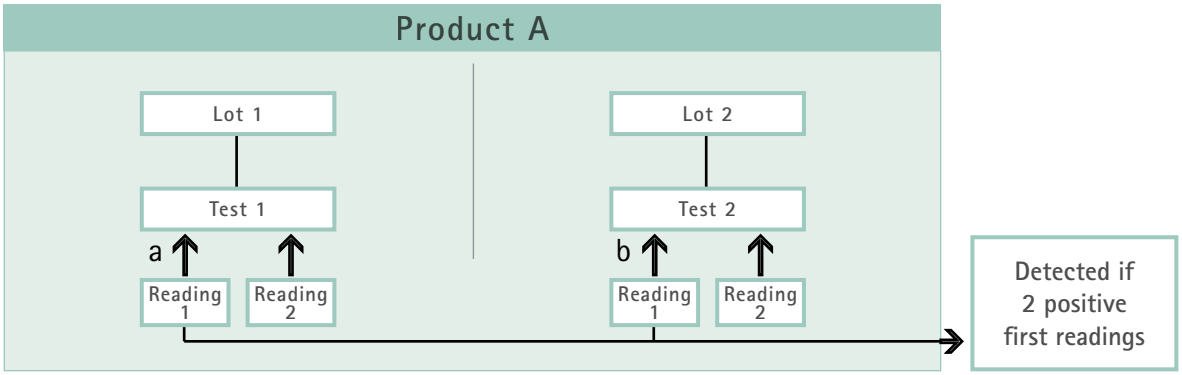


Based on the positive results of first test reading (2 tests per lot), the mean band intensity score =a+b+c+d/4 (excluding negative results).

[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

- 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 and
- buffer remains pooled in buffer well.

5.6.3 Assessement of performance against HRP2-negative *P. falciparum* panel

The parasite-positive panel comprised 40 *pfhrp2*-negative *P. falciparum* samples, 18 of which were *pfhrp3*-negative and 22 of which were *pfhrp3*-positive, with pLDH and aldolase antigen concentrations within the limits set for 200 parasites/µL.

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 (phases 1 and 2) and to each other's results (phases 1 and 2 and HRP2-negative panel). RDTs were labelled with a sample identification number and the date on which the 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 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 an 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 speciall database.

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

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

Individual product testing reports and raw data were sent to manufacturers on 15 May 2018 for a 30-day review period before production of the final report.

7. Quality assurance

Product testing follows standard operating procedures set during previous testing rounds on the basis of recommendations by expert consultants, with minor modifications by the steering committee before round 8 (*35*). 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.

Lots were analysed at temperatures above and below the manufacturer's recommended storage conditions.

7.2 Quality and objectivity of RDT readings

The results were read under good lighting by trained technicians who had been tested for visual acuity and used standard colour charts 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 parasite samples used in phases 1 and 2 were randomized with parasite-negative samples and re-labelled. The HRP2-negative panel was assembled and characterized only after the launch of round 8 testing, and therefore the sample type was known to the technicians at the time of testing. Reading of the RDT results by the first and second technician was blinded.

7.3 Quality of WHO specimen bank samples

Standard operating procedures were established for the preparation of all specimen bank samples (*34*). 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 h of thawing.

7.4 Quality of the product testing site

The Division of Parasitic Diseases and Malaria, Center for Global Health, CDC, is the main operating component of the Department of Health and Human Services of the USA 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: incorrect species identification and 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 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 a sample containing non-*P. falciparum (P. vivax)* parasites is tested. 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 virus, leishmania, Chagas trypanosomes, or schistosoma) and immunological factors (rheumatoid factor, anti-nuclear antibodies, anti-mouse antibodies and rapid plasma reagin, which is indicative of syphilis infection) (Table 2).

9.3 Band intensity

All positive test results were recorded with their band intensity against a standard reference chart, matched closely to line colour. On the basis of the results of the first reader, the distribution of band intensity results is presented as the mean

RESULTS

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

Pf/pan combination tests

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

Pf/Pv combination tests

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

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.

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 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 ten (*P. falciparum*) or four (*P. vivax*) against 2000 parasites/µL samples) and mean band intensity (for positive tests only based on the first reading) after the lots were stored at room temperature (21–24°C) and at 35°C and 45°C for two months.

9.7 Anomalies

The presence and frequency of commonly observed anomalies – red background, red background obscuring test line(s), incomplete clearing, incomplete migration, failed migration, strip misplaced in cassette (shift), specimen pad not seen in the sample window, ghost test line(s), diffuse test line(s), patchy broken line(s) and buffer remains pooled in buffer well – were routinely recorded for all round 8 products. Photographs and descriptions are shown in Fig. AS2.1.

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 1–8 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). An exception, however, is the HRP2-negative panel introduced in round 8, which contains no or negligible levels of HRP2 as compared with phase-2 panels but has comparable levels of pLDH ($p=0.27$, t-test) and a higher mean level of aldolase (mean difference = 2.2 ng/mL, 95% CI 1.4 – 3.0 ng/mL, $p<0.001$, Welch's t test).

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

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 different blood transfer devices may be provided with different products (*37*). This technique also ensures the consistency of testing by reducing the likelihood of operator error. As all samples in the panel used for phase 1 and 2 of 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 (*12–16*). 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, replicable 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 (*38*), which should be followed to improve the reproducibility and quality of the results.

12. Summary of results

Round 8 of WHO malaria RDT product testing provided results for 35 products evaluated against *P. falciparum* culture samples, and all except one of the products proceeded to evaluation against wild-type samples collected from parasitaemic patients on three continents, a large panel of parasite-negative samples and a panel of HRP2-negative *P. falciparum* 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 2017 and February 2018, approximately 59 020 RDTs were tested at the CDC.

The main results are presented in Tables 4, 5 and 9, 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*. Two products detected malaria species by pan-LDH only, 23 products detected *P. falciparum* species by HRP2-only, and seven detected *P. falciparum* species by HRP2 and Pf-LDH, on either the same or separate test lines. Three products detected *P.falciparum* by Pf-LDH only. As only tests against *P. falciparum* and *P. vivax* were evaluated, the evaluation does not indicate whether a product intended to detect other species, i.e. *P. malariae* or *P. ovale*, could do so. The detailed results of phases 1 and 2 and against the HRP2-negative panel are given in Annexes 3 and 4, respectively. The data are shown graphically in Figs. 9–33.

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 performance criteria (Box 3); WHO prequalification status is also indicated in Table S2, as this is now a requirement for WHO procurement of HRP2-based *P. falciparum*-only RDTs. 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 key results of the evaluation are listed below.

- The overall range of results against phase 2 wild-type *P. falciparum* and negative samples, including *P. falciparum* PDS, *P. falciparum* positivity rate and heat stability, were similar to those in rounds 1–7 (*3–9*); the false-positivity rates and *P. vivax* PDS and *P. vivax* positivity rates were similar to those in round 7 and better than in previous rounds.
- The median phase 2 PDS for *P. falciparum* at low parasite densities in round 8 (88.0%) was slightly lower than in round 7 (89.5%) and slightly higher than in rounds 5 and 6 (both 86%). No products in round 8 scored a PDS of 100% for the *P. falciparum* test line. The phase-2 PDS for *P. vivax* at low densities has improved consistently since round 1 (median, 30%): the results for rounds 2, 3, 4, 5, 6, 7 and 8 were 75.0%, 51.4%, 61.8%, 65.7%, 82.9%, 90.0% and 95.7%, respectively. Six products achieved 100% PDS on their pan-LDH and Pv-LDH lines when tested against *P. vivax* but had lower scores for their *P. falciparum* test lines. The median false-positive rate on clean negative samples, samples containing other infectious agents and samples containing immunological factors was 0%.
- In phase 2, four products did not meet WHO performance criteria at low parasitaemia against *P. falciparum*, while two products did not meet WHO performance criteria for detection of the low-density *P. vivax* panel.
- The average phase-2 PDS was 86.3% for products that detect HRP2 in *P. falciparum* only and 88.8% for those that detect HRP2 and Pf-LDH. On dual line tests, the HRP2 line had a higher PDS and was the driver of the high PDS score.
- Several combination tests achieved the phase-2 PDS at the upper end of the range for both *P. falciparum* and *P. vivax*.
- Of the three products that target Pf-LDH only for detection of *P. falciparum*, two did not meet the WHO performance

criteria at low parasitaemia. Two products that detect pan-LDH achieved 98% PDS against *P. falciparum* at low density.

- Incomplete clearing and red background (not obscuring test lines) were the most common anomalies, seen in 100% and 94% of products, respectively.
- In terms of lot-to-lot variation, the average difference in positivity rate was 2.0 percentage points among *P. falciparum* and 2.4 percentage points among *P. vivax* samples in round 8.
- *P. falciparum*-only RDTs and the *P. falciparum* test lines of combination tests demonstrated excellent thermal stability against low- and high-density samples (Figs 20–23), with the exception of two products at low density *P.falciparum,* both of which had a low PDS as baseline, as did the Pv-LDH and pan-LDH lines of combination tests (Figs 26–29). In contrast, the pan-LDH test lines of combination tests often performed poorly in detecting the low-density *P. falciparum* sample at baseline, with both increases and decreases in performance after thermal incubation (Fig. 24). These tests performed well against the high-density *P. falciparum* samples and were heat stable (Fig. 25).
- Despite comparable pLDH antigen concentrations, the performance (both PDS and positivity rate) of non-HRP2 RDTs against the HRP2-negative *P. falciparum* panel was less good than against the phase-2 wild-type *P. falciparum* panel (Fig. 31). Only the pan-LDH-only tests met WHO performance criteria in both panels. Further investigations are required to find an explanation for this unexpected result, with additional evaluations of more geographically diverse clinical blood samples.
- Several HRP2-RDTs detected HRP2-negative samples because of cross-reactivity with HRP3, and, in many cases, the HRP2-negative samples were detected by the pan-LDH line of combination HRP2 or pf-LDH/pan-LDH tests (Fig. 32).

Table 4: Summary of phase-1 performance of 35 malaria RDTs against 20 cultured *P. falciparum* lines at low (200) and high (2000) parasite densities (parasites/µL)

Product	Product code	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200.0 parasites/µL	2000.0 parasites/µL	200.0 parasites/µL (n=80)	2000.0 parasites/µL (n=40)	
Pf only							
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	100.0	100.0	NA	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio Inc.	100.0.0 (100/5)[c]	100.0 (100/95)[c]	NA	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	100.0	100.0	NA	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	100.0	100.0	NA	NA	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO. INC	95.0	100.0	NA	NA	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II)[d]	RK MAL 025-25	Advy Chemical Pvt. Ltd.	90.0 (85/45)[c]	100.0 (100/100)[c]	NA	NA	0.5
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	5.0	100.0	NA	NA	0.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	95.0	100.0	NA	NA	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	100.0 (100/45)[c]	100.0 (100/100)[c]	NA	NA	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	95.0	100.0	NA	NA	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	100.0	100.0	NA	NA	0.5
Pf and pan							
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	95.0	100.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO. INC	100.0	100.0	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	55.0	100.0	0.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	75.0	100.0	0.0	0.0	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	95.0	100.0	1.3	0.0	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	25.0	100.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	100.0	100.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	100.0	100.0	0.0	0.0 (39)	0.5
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	100.0	100.0	0.0	0.0	0.0
Pf and Pv/Pvom							
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	100.0	100.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	100.0	100.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co.. Ltd.	100.0	100.0	0.0	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	100.0	100.0	0.0	0.0	0.0

Table 4 *(continued)*

Product	Product code	Manufacturer	Panel detection score[a] (n=20)		False-positive non-Pf infection[b] (%)		Invalid rate (%) (n=120)
			200.0 parasites/µL	2000.0 parasites/µL	200.0 parasites/µL (n=80)	2000.0 parasites/µL (n=40)	
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	100.0	100.0	0.0	0.0	0.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	100.0	95.0	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	100.0	100.0	0.0 (79)	0.0 (38)	4.5
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	100.0	100.0	0.0 (79)	0.0	0.5
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	100.0	100.0	57.5	35.0	0.0
Pan only							
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	95.0	100.0	NA	NA	0.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO. INC	100.0	100.0	NA	NA	0.0
Pf. Pf and Pv							
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	100.0 (100/50)[c]	100.0 (100/100)[c]	0.0	0.0	0.0

NA. not applicable

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

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

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

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

[d] Product had high false positive rates on 20 clean negative samples from Phase 1; therefore, it was not included in Phase 2

Table 5: Summary of phase-2 performance of 34 malaria RDTs against wild-type (clinical) *P. falciparum* and *P. vivax* samples at low (200) and high (2000[a]) parasite density (parasites/µL) and *Plasmodium* spp. negative samples

Product	Product code	Manufacturer	Panel detection score[b]				False positive rates (%)				Total false positive rates[e] (%)	Invalid rate (%) (n=1210)
			200 parasites/µL		2000 parasites/µL		200 parasites/µL		2000 parasites/µL		Clean negative samples	
							Pf samples	Pv samples	Pf samples	Pv samples		
			Pf samples (n=100)	Pv samples (n=35)	Pf samples (n=100)[a]	Pv samples (n=35)	False positive non Pf infection[c] (n=400)	False positive Pf infection[d] (n=140)	False positive non Pf infection[c] (n=200)	False positive Pf infection[d] (n=70)	False positive *Plasmodium* spp. infection (n=208)	
Pf only												
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	92.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.1
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio Inc.	82.0 (81/40)[f]	NA	100.0 (99/95)[f]	NA	NA	1.4	NA	2.9	0.5	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	96.0	NA	100.0	NA	NA	0.0	NA	1.4	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	10.0	NA	88.0	NA	NA	5.0	NA	12.9	5.8	0.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	94.0	NA	100.0	NA	NA	1.4	NA	4.3	3.4 (207)	0.1
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	90.0 (88/71)[f]	NA	100.0 (99/98)[f]	NA	NA	0.0	NA	0.0	0.0	0.1
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	87.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	93.0	NA	99.0	NA	NA	0.0 (139)	NA	1.4	1.0	0.1
Pf and pan												
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	87.0	94.3	100.0	100.0	3.0	0.7	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	90.0	97.1	99.0	97.1	2.0	0.0	0.5	1.4	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	83.0	97.1	100.0	100.0	2.0	0.0 (139)	0.0	0.0	1.0	0.1
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	87.0	94.3	100.0	100.0	3.0	0.7	0.0	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	62.0	65.7	97.0	100.0	0.5	0.7	2.0	0.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	63.0	91.4	98.0	100.0	0.5	0.0	0.0	0.0	0.5	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	83.0	100.0	99.0	97.1	1.3	0.0	0.5	1.4	1.4	0.1
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	27.0	100.0	96.0	100.0	10.3	0.0	1.5	0.0	1.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	91.0	94.3	100.0	97.1	0.0	0.7	0.0	1.4	0.5	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	88.0	100.0	99.0	100.0	0.0	0.0	0.5	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	92.0	80.0	99.0	100.0	0.5 (398)	0.7 (139)	0.5	0.0	10.6	0.2
Pf and Pv/Pvom												
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	86.0	85.7	99.0	100.0	1.0	0.0	1.0	0.0 (69)	0.0	0.1

Table 5: Summary phase-2 performance of 34 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 False positive non Pf infection[c] (n=400)	Pv samples False positive Pf infection[d] (n=140)	Pf samples False positive non Pf infection[c] (n=200)	Pv samples False positive Pf infection[d] (n=70)	False positive *Plasmodium* spp. infection (n=208)	
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	87.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	87.0	100.0	100.0	100.0	3.0	0.0	0.5	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	88.0	74.3	99.0	97.1	1.8	0.0	0 (199)	1.4	0.0	0.1
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	95.0	100.0	100.0	100.0	0.8	0.0	0.0	0.0	0.5	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	94.0	100.0	100.0	100.0	0.8 (399)	0.7	0.5	0.0	1.0	0.1
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	83.0	77.1	97.0	97.1	0.3	0.0	0.0	1.4	1.9	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	88.0	91.4	97.0	100.0	0.3 (399)	0.7 (139)	1.5	0.0	0.0 (201)	0.7
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	85.0	100.0	99.0	100.0	0.5	0.0	0.5	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	84.0	80.0	97.0	100.0	37.3	12.9	20.0	2.9	31.7	0.0
Pan only												
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	98.0	97.1	100.0	100.0	NA	NA	NA	NA	9.1	0.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	98.0	85.7	100.0	85.7	NA	NA	NA	NA	5.3	0.0
Pf, Pf and Pv												
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	89.0 (89/62)[f]	97.1	100.0 (99/99)[f]	100.0	0.0	0.0	0.0	0.0	0.0	0.0

NA, not applicable

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

[a] 2 (2%) 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-LDH band, respectively

Performance measure	Recommended WHO performance 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

13. Results for phases 1 and 2, heat stability, ease of use, anomalies and inter-lot variation

13.1 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 (5–100%) at low parasite density (200 parasites/µL), three products having a PDS < 75% (Fig. 9). One product, EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II) (RK MAL 025-25), had a > 50% false-positive rate against clean negative samples and therefore did not proceed to phase 2.

13.2 Phase 2: Wild-type panel

13.2.1 *P. falciparum* detection

All products in round 8 were designed to detect *P. falciparum*. All except one had very high scores for detection of the high-density sample set, with a PDS ≥ 97%. Nine of the 10 *P. falciparum*-only products achieved a PDS ≥ 75% against samples with low parasite density (Table 5, Fig. 10). Futhermore, 21 of the 24 combination and pan-only tests met WHO performance criteria for *P. falciparum*, with a PDS of 83–98% (Table 5, Fig. 10).

Only one of three tests met the WHO performance criteria for detection of *P. falciparum* exclusively with Pf-LDH. The PDS of these products were 10%, 27% and 83%, and the false-positive rates were 5.8%, 1.0% and 1.0%, respectively. For three products with HRP2 and pf-LDH on separate test lines for detection of *P. falciparum*, the PDS based on pf-LDH tests lines was 40%, 71% and 62%, and the PDS for both test lines was 82%, 90% and 89%, respectively.

13.2.2. *P. vivax* detection

Fig. 11 shows that all the products designed to detect *P. vivax* consistently detected ≥ 75% at high parasite density (2000 parasites/µL), and 22/24 (91.7%) achieved the same PDS against samples with 200 parasites/µL. The overall detection rate of low-parasite density wild-type *P. vivax* samples was slightly higher than that for *P. falciparum*. At a low parasite density (200 parasites/µL), 17 products had a PDS ≥ 90% (Table 5, Fig. 11), which is an improvement on round-7 results, in which 13/27 (48%) of products had a PDS ≥ 90%, and 8/27 (26%) of products had a PDS < 75%.

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

Of the 24 pan-specific and combination tests, 21 (88%) 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 2000 parasites/µL.

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

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).

13.3 Band intensity

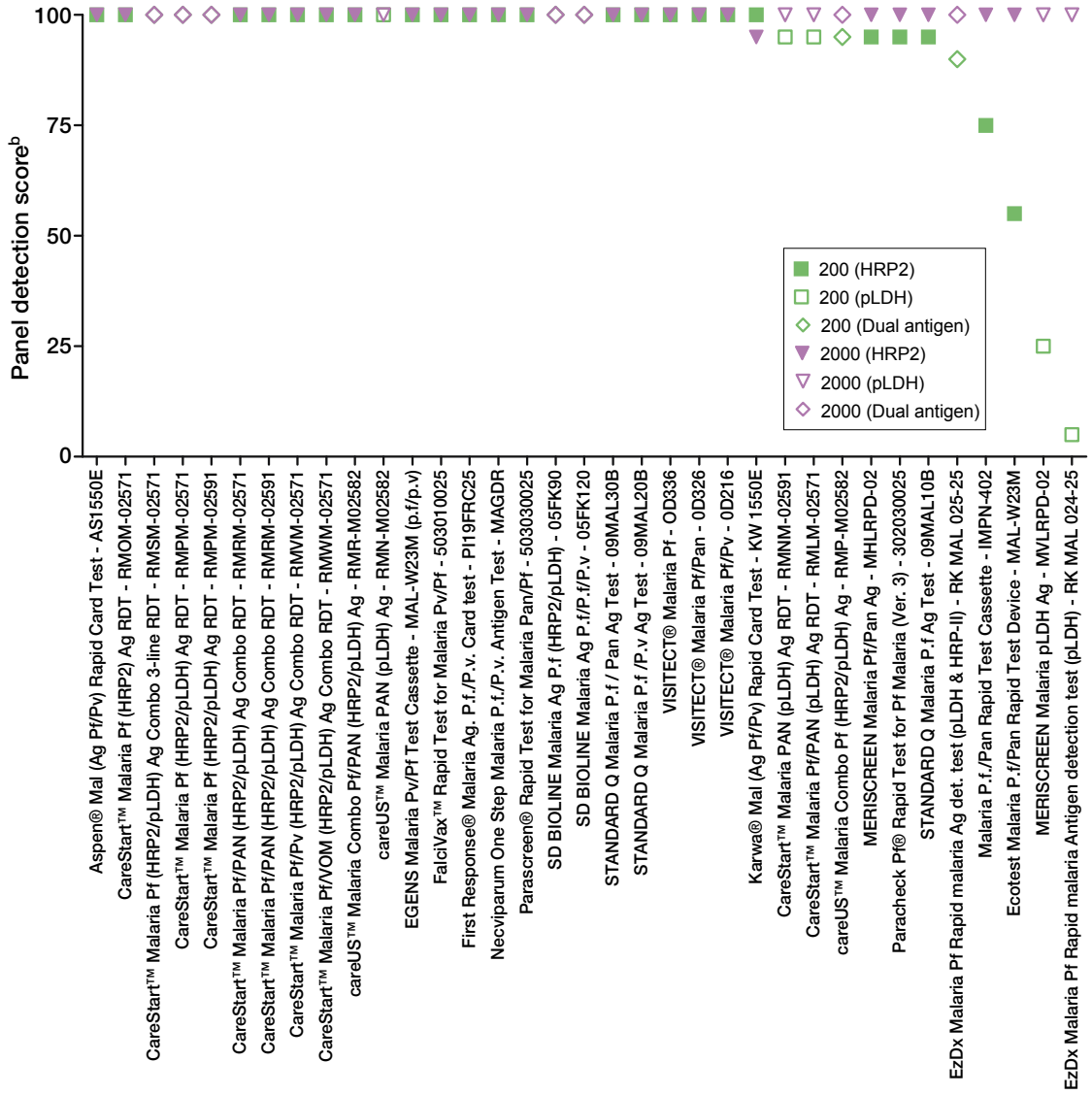
Although RDTs do not provide quantitative results, the technicians graded positive results according to a standard colour chart and calculated the mean band intensity for positive results (Annex 4, Tables A3.2 (for phase 1), A4.2 and A4.3 (for phase 2)). A positive correlation was found between the PDS and band intensity (Spearman rank correlation, $r = 0.790$, $p < 0.001$ for the *P. falciparum* phase-2 panel and $r = 0.705$, $p < 0.001$ 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, 63.7% (2456/3858) gave positive results on both the *P. falciparum* and pan test bands, and 34.0% (1310/3858) were positive only on the *P. falciparum* test band. A small proportion (2.4%, 92/3858) were positive only on the pan test band.

When both the pan test band and *P. falciparum* test band in the combination products was positive, the intensity of the band was the same as that of the *P. falciparum* test band in 24.2% of tests, while 31.6%, 30.5% and 13.1% of the pan test bands were one, two and three intensities lower than the corresponding *P. falciparum* test bands, respectively. Only 0.5% of tests had a pan band intensity greater than the corresponding *P. falciparum* test band.

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

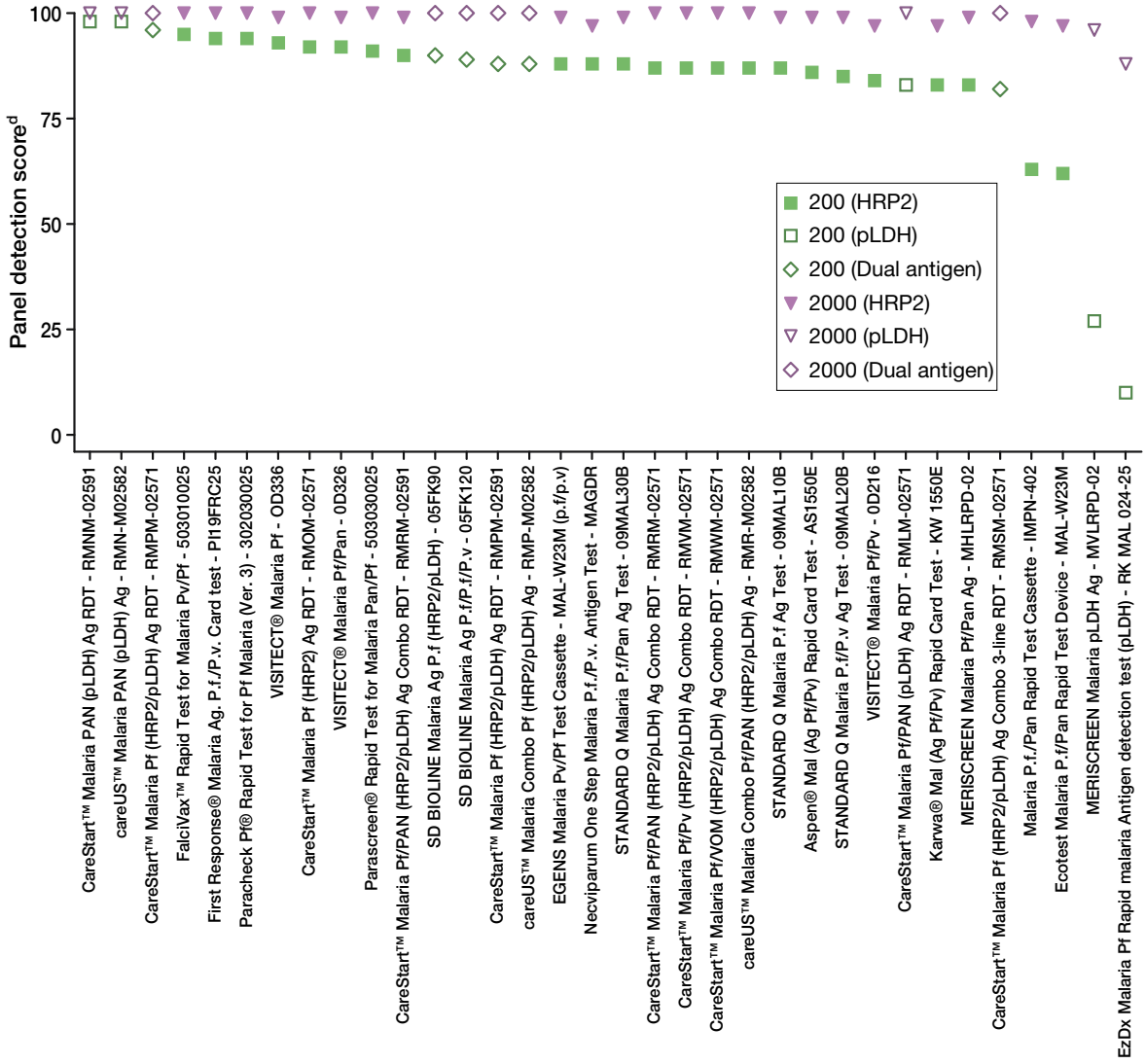
Figure 9: Phase-1 *P. falciparum* panel detection score of malaria RDTs[a] at low (200) and high (2000) parasite density (parasites/µL)



[a] 30/35 products target HRP2 for *P. falciparum* detection. Three products target only Pf-LDH for falciparum detection including RMLM-02571, RK MAL 024-25, MVL RPD-02. Three products target both HRP2 and Pf-LDH on the same test line (RMPM-02571, RMPM-02591, RMPM-02582) and four products target both HRP2 and Pf-LDH but on separate test lines (RMSM-02571, RK MAL 025-25, 05FK120, 05FK90). For the latter products, individual test line 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.

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]



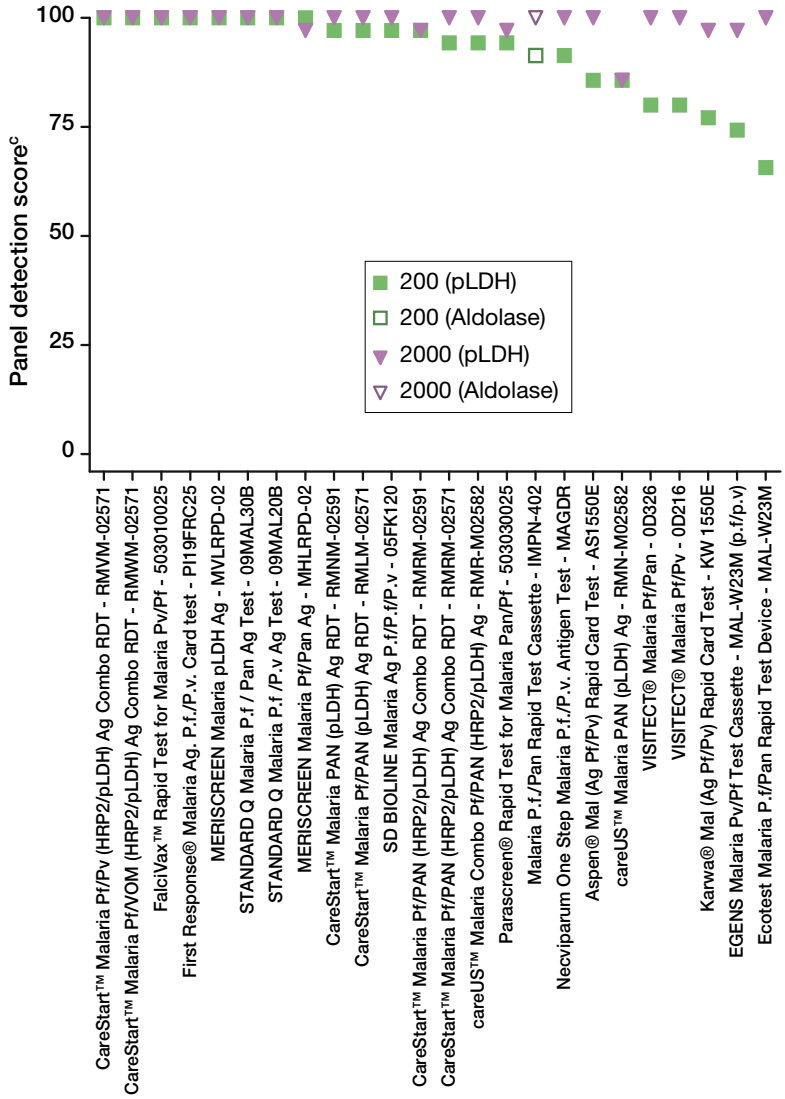
[a] 2 (2%) of the 100 *P. falciparum* high parasite density dilution samples were at 5000 parasites/µL rather than 2000

[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] 29/34 products target HRP2 for *P. falciparum* detection. Three products target both HRP2 and Pf-LDH on the same test line (RMPM-02571, RMPM-02591, RMPM-02582) and three products target both HRP2 and Pf-LDH but on separate test lines (RMSM-02571, 05FK120, 05FK90). For the latter products, individual test line 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.

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

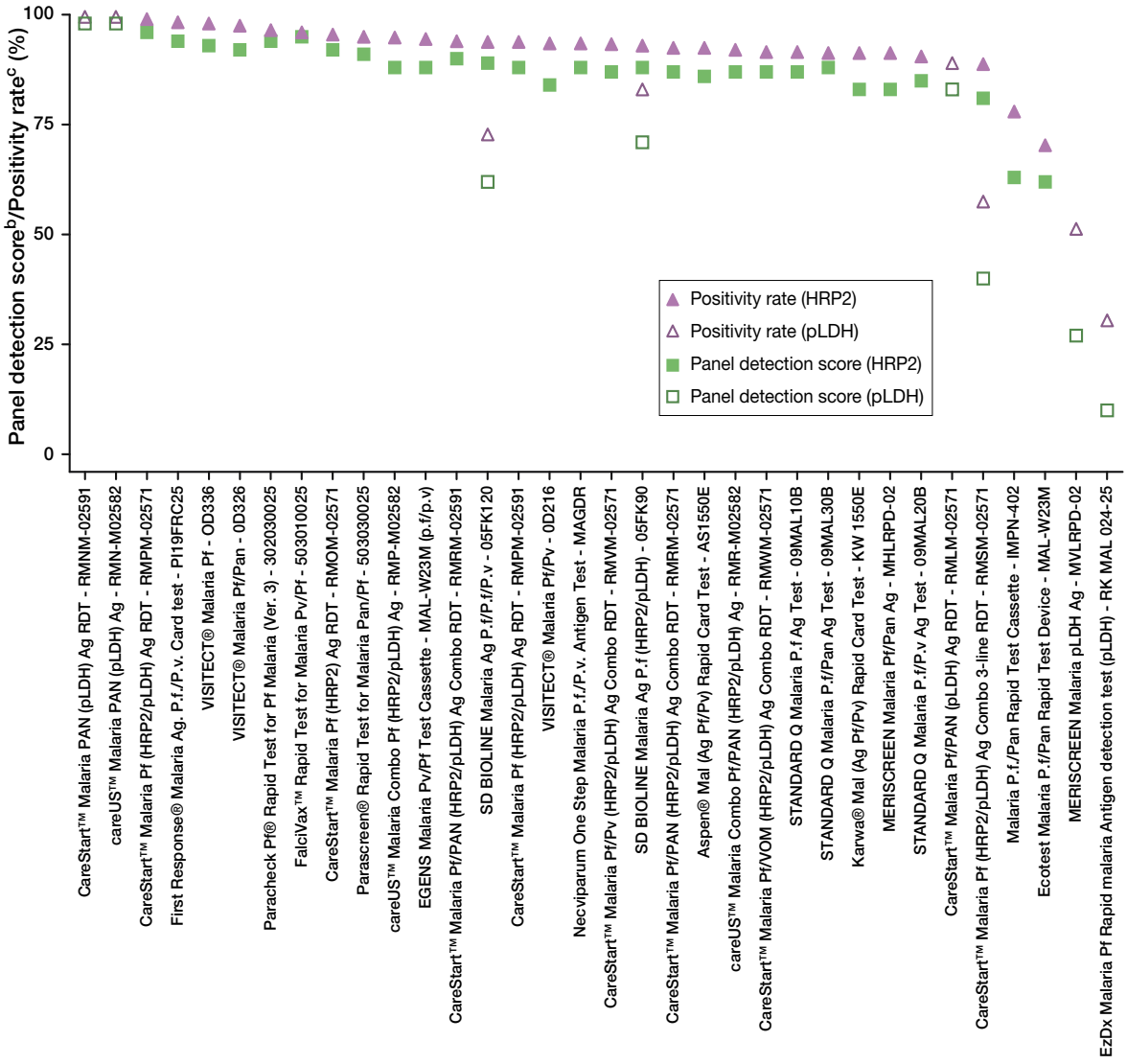


[a] Phase-2 evaluation panel consisted of 35 clinical blood samples containing wild-type *P. vivax*; RDTs performed = 2 tests x 2 lots at 200 p/µL and 1 test x 2 lots at 2000 p/µL;

[b] All RDTs target pan-LDH, Pv-LDH, aldolase

[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.

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

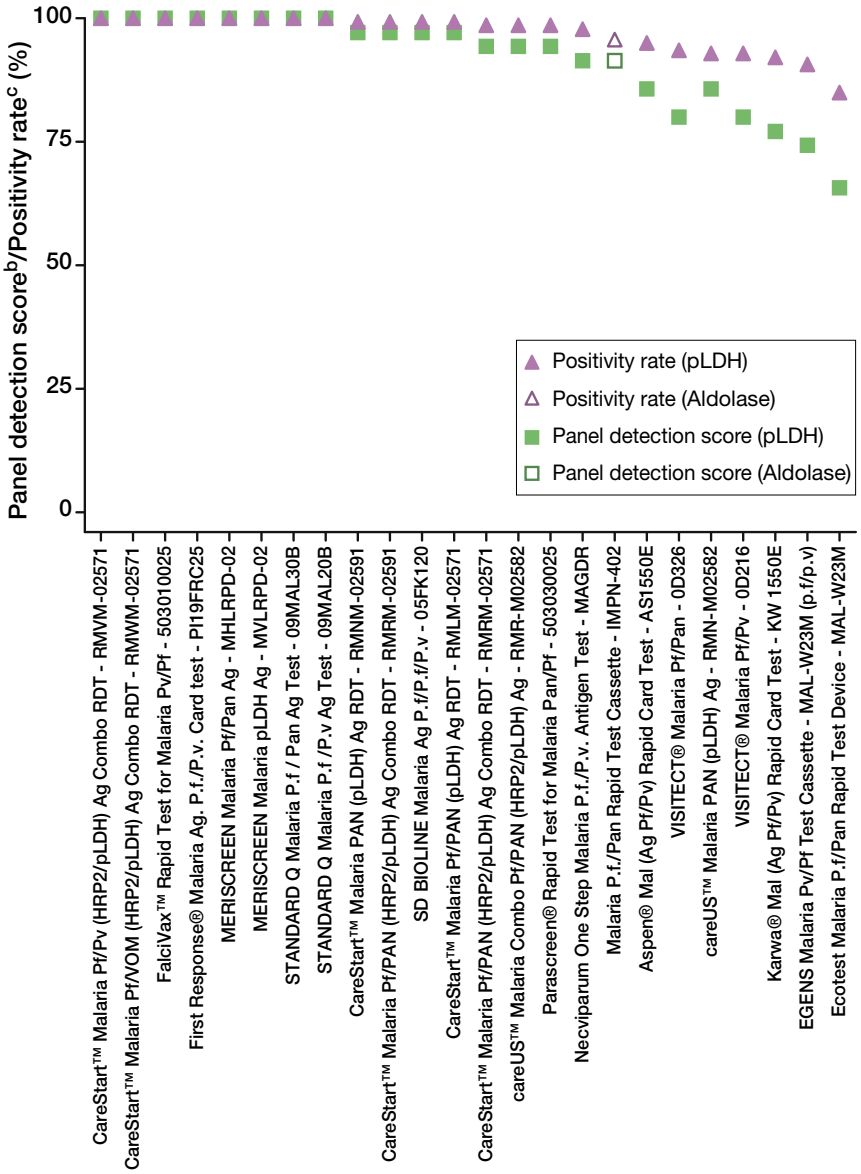


[a] Phase-2 evaluation panel consisted of 100 clinical blood samples containing wild-type *P. falciparum*. RDTs performed = 2 tests x 2 lots at 200 p/µL and 1 test x 2 lots at 2000 p/µL;

[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).

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;

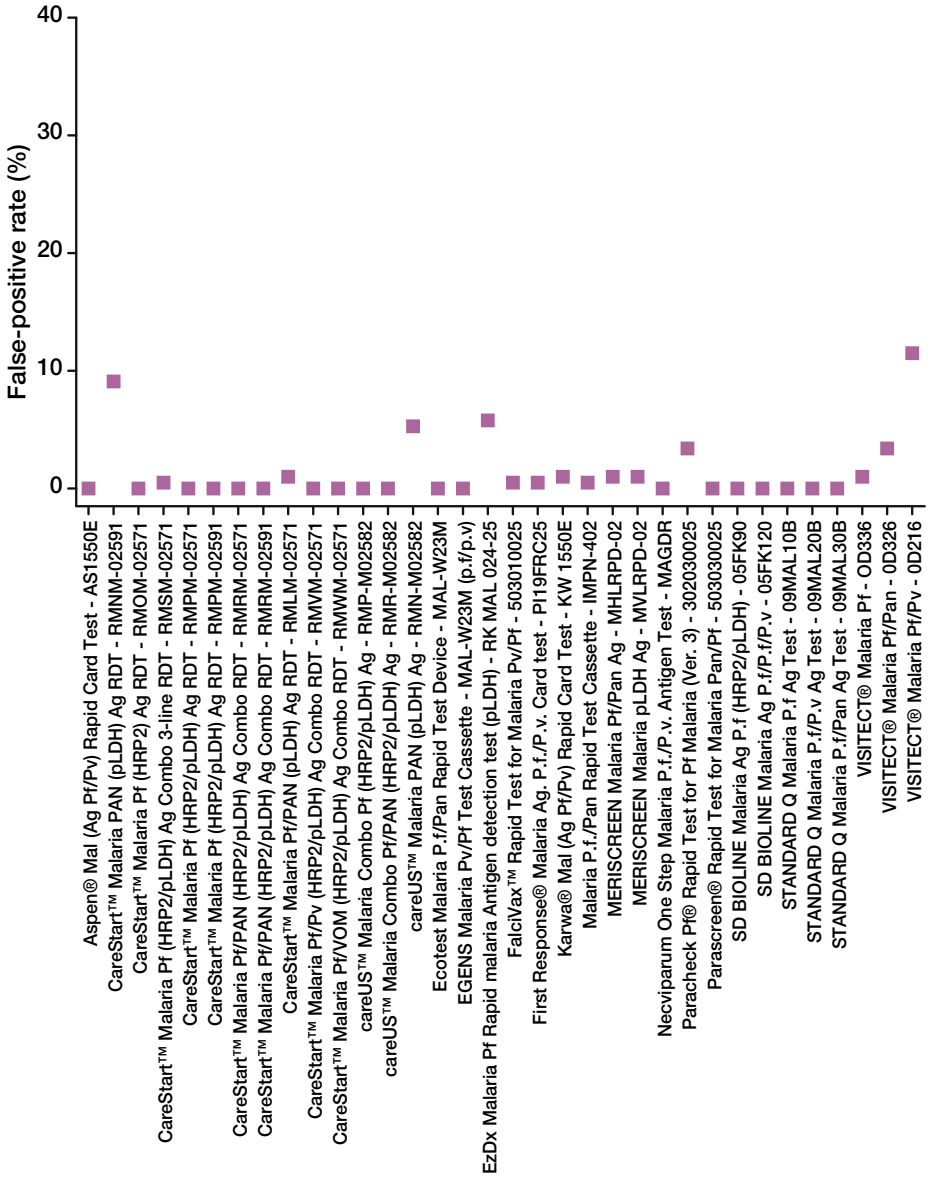
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive;

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

13.4 False-positive rates

One of the products had a false-positive rate for the *P. falciparum* test line > 10% with 52 clean negative samples (Fig. 14); two products had false-positive rates > 10% with pan or *P. vivax* test lines (Fig. 15); six products had false-positive rates > 5.0% (for one or both lots) against samples containing immunological factors, while three of these had a false-positive rate > 15%. This is slightly better than in round 7. False positivity was seen predominantly for samples containing immunological factors (seven of the eight instances of false positivity, > 10%); however, only 27 negative samples contained immunological factors.

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

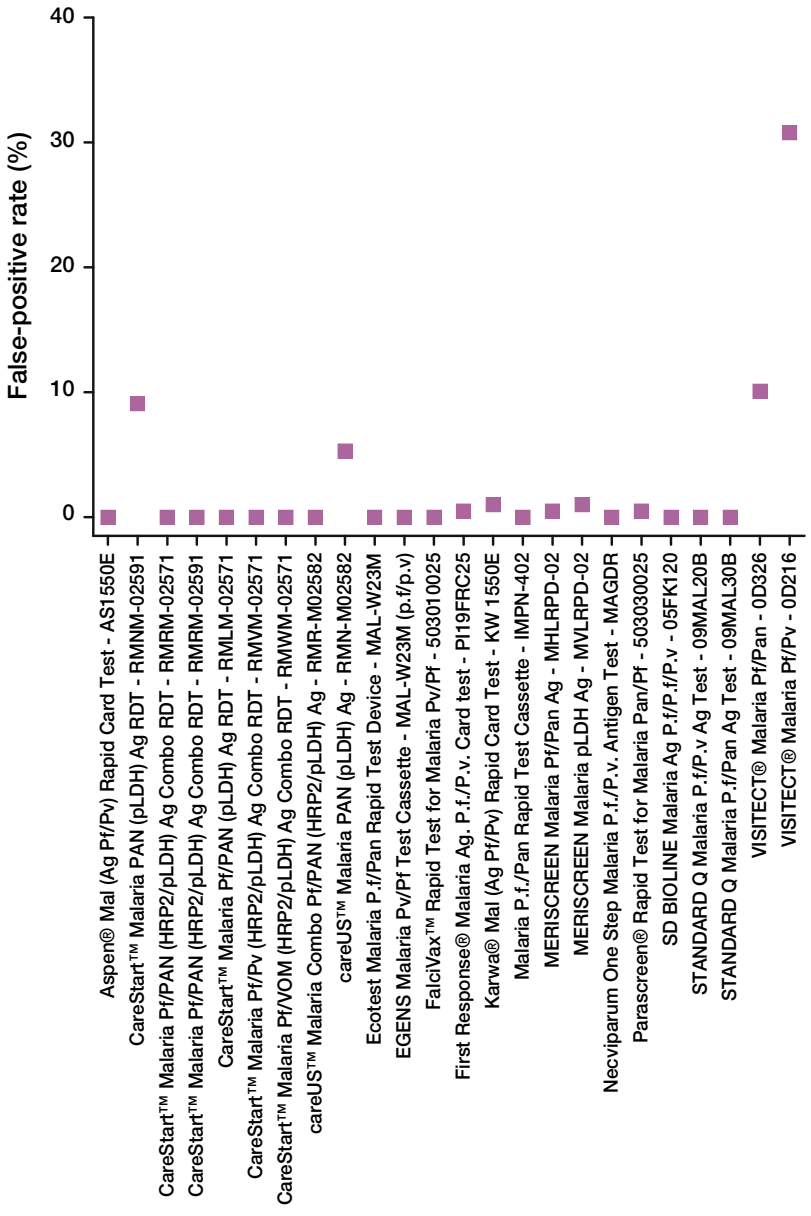


[a] Phase-2 evaluation panel included 100 *Plasmodium* spp.-negative samples, of which 52 were clean negatives from healthy volunteers with no known current illness or blood abnormality.

The false-positivity rates for samples containing non-*Plasmodium* spp. were similar to those in round 7. In only three products was the false-positivity rate > 3.0%, with false-positivity rates of 3.6%, 6.0% and 9.5% between the two lots. False positivity was seen against three of the samples of infectious agents used: schistosomasis flatworms (five products), Chagas disease trypanosomes (three products) and dengue virus (three products), and no false-positives were seen against leishmaniasis trypanosomes. A total of 21 samples contained non-*Plasmodium* infectious agents.

For detailed information on the blood abnormalities and pathogens that generated false-positive results in specific products, see Annex 4 (Tables A4.6–A4.9).

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

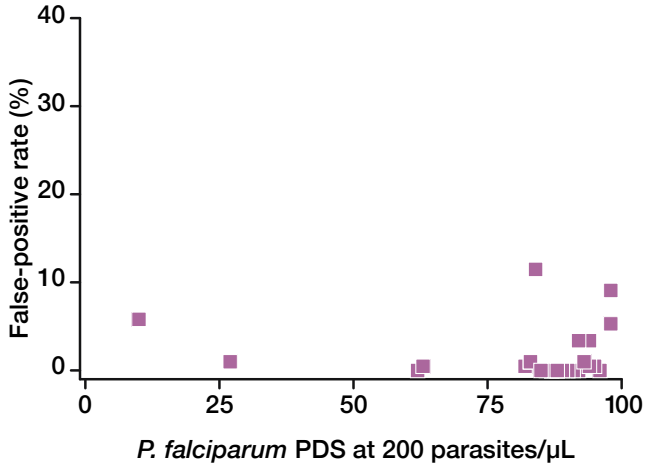


[a] Phase-2 evaluation panel included 100 *Plasmodium* spp.-negative samples of which 52 were clean negatives, from healthy volunteers with no known current illness or blood abnormality.

Products were assessed for false-positivity rates against various species of *Plasmodium* (Tables 5, A4.4 and A4.5). Eleven products showed false-positive *P. falciparum* infection for a *P. vivax* sample at low density (200 parasites/µL); however, seven of the rates were < 1%. One product had an overall false-positivity rate of 5.0% and one of 12.9%. Eleven products incorrectly identified the species at the higher concentration (2000 parasites/µL).

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

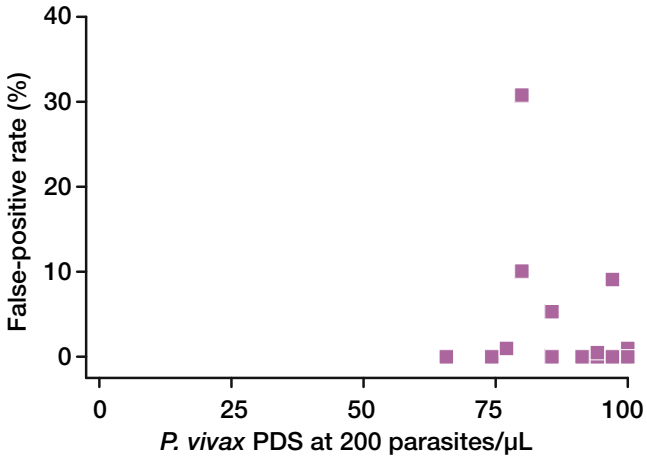
Figure 16: Phase-2 *P. falciparum* false-positive rate[a] versus *P. falciparum* panel detection score[b] at low parasite density (200 parasites/µL)



[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;

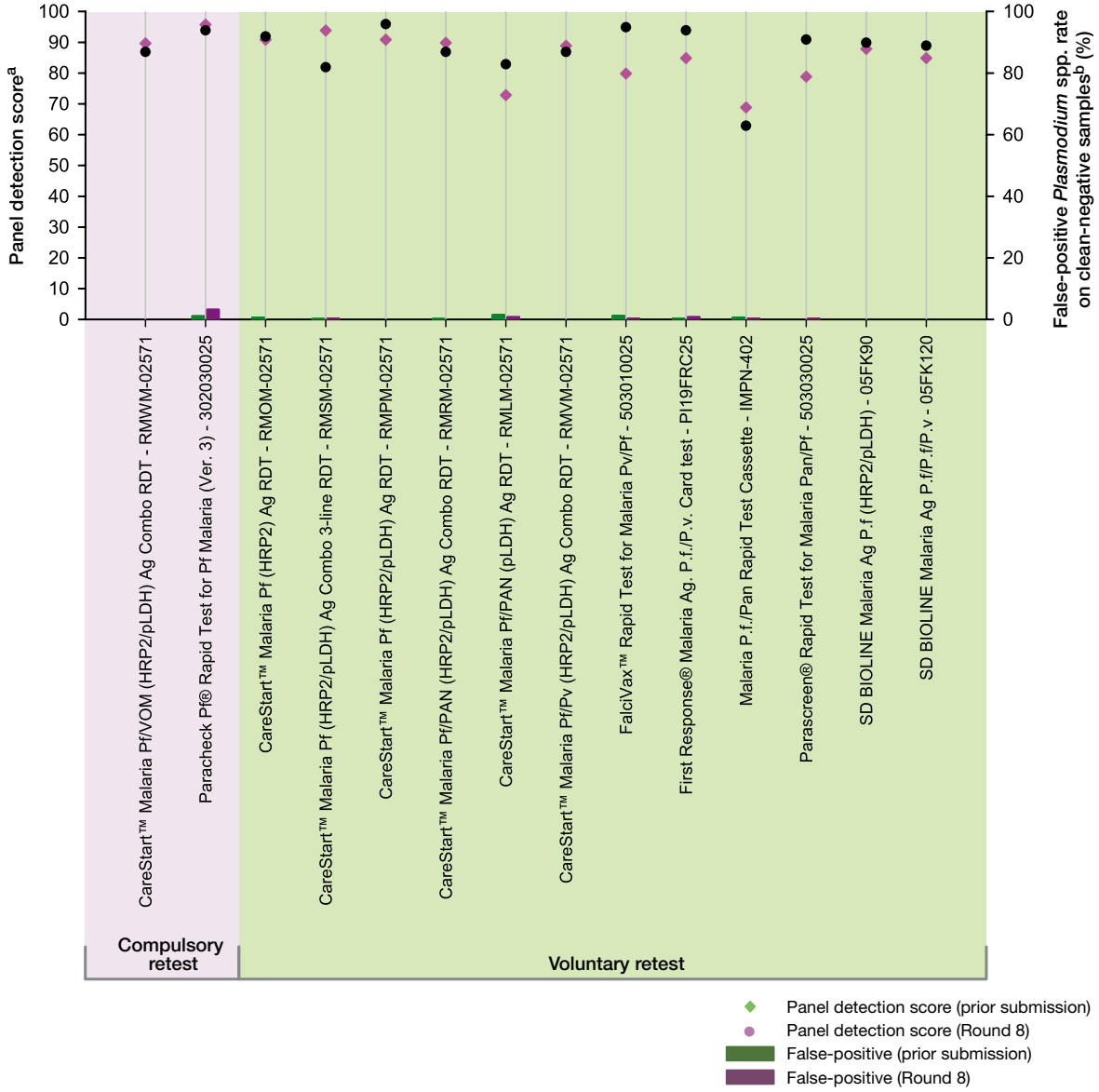
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.

13.5 Performance of resubmitted products

Of the 35 products submitted in round 8, 14 (40%) had been evaluated previously, and two were compulsory resubmissions. For four of the resubmissions, this was the second testing, and ten 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.

In round 8, both products submitted for compulsory retesting had a slightly lower PDS than in the previous evaluation round, one by 2.8 percentage points and one by 1.9 percentage points for detection of clinical *P. falciparum* at 200 parasites/µL. Only one of the tests also targeted *P. vivax* at 200 parasites/µL, showing an increase of 8.8 percentage points. One product had an increase in the false-positive rate of clean negatives of 2.1 percentage points, while the other product had 0.0% in both rounds.

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

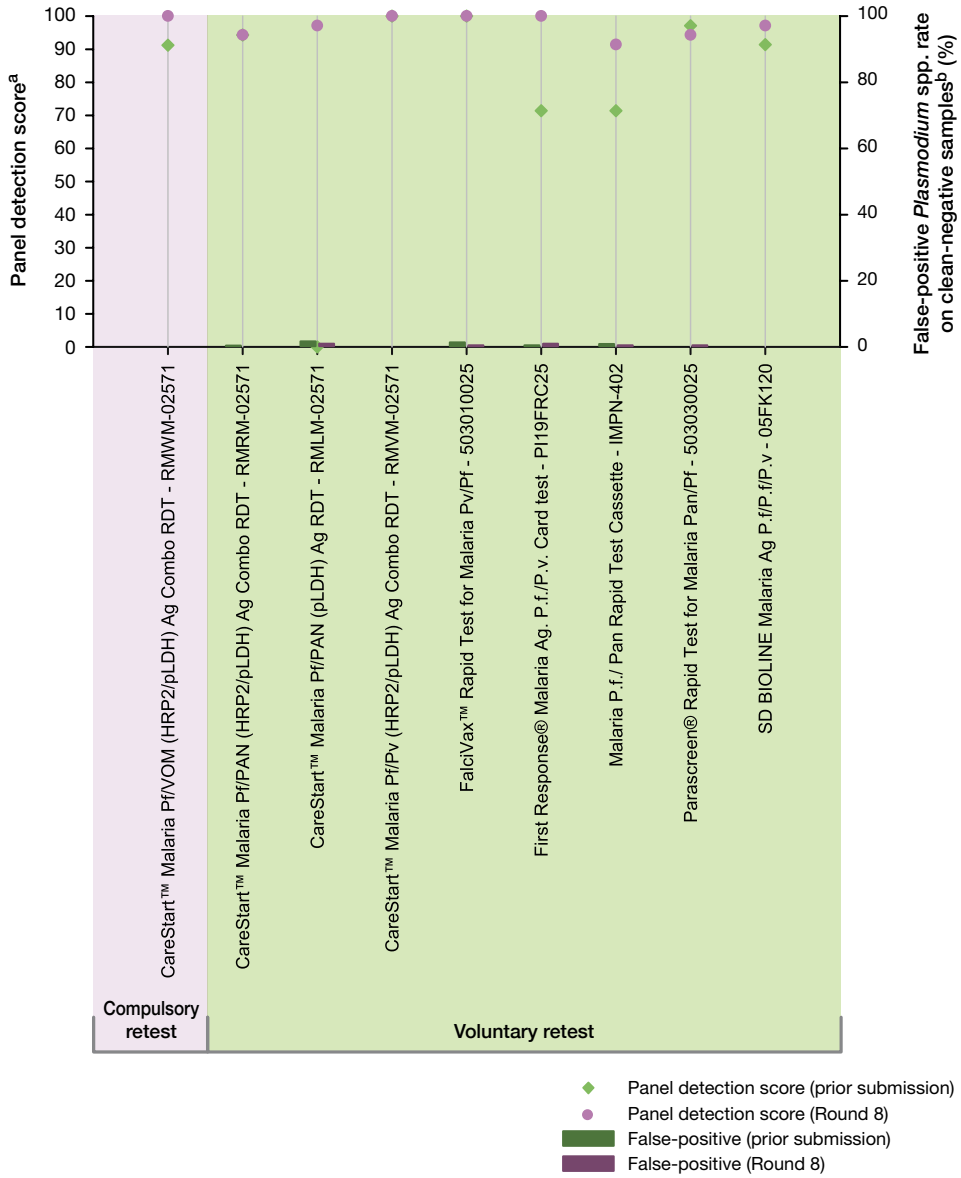


[a] Panel detection score - A sample is considered detected only if all RDTs from both lots read by the first technician, at the minimum specified reading time, are positive.
[b] Clean-negative blood samples from healthy volunteers with no known current illness or blood abnormality.

For the 12 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, $r = 0.183$, $p = 0.570$). The median change in detection of *P. falciparum* was +3.0% (range, –12.0% to 15.0%), which was not significantly different from 0 (Wilcoxon signed rank test, $p = 0.239$). Most of the products (8/12) detected *P. vivax*, and detection of this parasite improved overall (median change, 2.8%; range, –2.8% to 97.1%), which was not statistically significant (Wilcoxon signed rank test, $p = 0.080$). No statistically significant correlation was found between the PDS of consecutive submissions of tests against *P. vivax* at lower parasite density (Spearman rank correlation, $r = 0.325$, $p = 0.432$).

On re-testing, the false-positivity rate against clean negative samples was unchanged or improved for over half the resubmitted products (9/14); the median change in false-positivity rate was +0.0%. All the changes on re-testing were small, with a maximum of 2.1 percentage points.

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.

13.6 Heat stability

13.6.1 Summary

A single *P. falciparum* culture sample and single wild-type *P. vivax* sample were used as reference samples for assessing 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 8 was the third round 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.

13.6.2 *Plasmodium falciparum*

Nine of the 10 *P. falciparum*-only RDTs test line were heat stable. Thus, they detected a cultured *P. falciparum* sample the same number of times as at baseline when stored at room temperature (21–24°C) or at 35°C or 45°C (with 75% humidity) for two months (Fig. 20). All the heat-stable *P. falciparum*-only products had an HRP2 test line, while the non-heat stable product had a pf-LDH line only. The number of positive tests decreased from 21/30 at baseline to 10/30 at 45°C.

Of the 22 combination tests, 20 had an HRP2-detecting line. Of these, 18 tests were heat stable against a cultured *P. falciparum* sample, and two products showed only slight deterioration after storage at 45°C (Fig. 22). Of the two combination tests that did not have an HRP2 line, one showed no deterioration and the other showed better performance at 35°C and further improvement at 45°C.

Overall, products that detect *P. falciparum* were more heat stable at the higher density. None of the 32 products showed deterioration and had 10/10 detection after storage at 45°C.

Eleven combination and two single-test-line products had pan lines (either pLDH or aldolase). Six of these products had good (i.e. scored at least 28/30) baseline pan lines for the low-density *P. falciparum* sample, including the two pan-LDH-only tests (Fig. 24). Five of these products showed minimal deterioriation. Five products 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, four products having higher scores after storage at 35°C and 45°C, suggesting that they were on the borderline of visibility.

Overall, the stability of pan-LDH-detecting test lines was poorer than that of HRP2-detecting test lines (Figs 20–25).

13.6.3 *Plasmodium vivax*

Testing of the heat stability of *P. vivax*-detecting lines with a *P. vivax* clinical sample was introduced in round 6. Ten of the 11 products with a *P. vivax* line showed no deterioration at room temperature, 35°C or 45°C when tested against low-density wild-type *P. vivax*, with a score of 8/8 samples detected throughout (Fig. 26). One product, a combination test for *P. falciparum* and *P. vivax*, was stable at room temperature and at 35°C but showed slight deterioriation at 45°C for 6/8 samples detected. All products were heat stable at the higher density of *P. vivax*, with a score of 4/4 samples detected throughout and at baseline, room temperature, 35°C and 45°C storage, except for one product, which had a score of 4/4 samples detected at all temperatures except 35°C, for a score of 3/4 samples detected.

All 13 products with a pan test line had a score of 8/8 samples detected at baseline, and 12 products showed no deterioration of the pan test line for low-density *P. vivax* detection at room temperature, 35°C or 45°C. One sample showed very slight deterioration after storage at 45°C, with 7/8 samples detected. All 13 products were heat stable on the pan test line at the higher density of *P. vivax*, with a score of 4/4 samples detected throughout and at baseline, room temperature, 35°C and 45°C storage.

Overall, both *P. falciparum*- and *P. vivax*-detecting products appeared to be more stable against samples with high (2000 parasites/µL) rather than low (200 parasites/µL) parasite density, as minor deterioration was not apparent at high parasite density. The stability of pan-LDH-detecting lines was poorer against *P. falciparum* than against *P. vivax* samples. Pf-LDH lines were less stable than HRP2 lines against low-density *P. falciparum*.

Table 6a: Heat stability testing results for 34 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																		
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	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 RDT	RMSM-02571	Access Bio Inc.	30 (30/0)[b]	30 (30/0)[b]	30 (30/0)[b]	30 (30/0)[b]	NA	NA	NA	NA	10 (10/8)[b]	10 (10/2)[b]	10 (10/10)[b]	10 (10/2)[b]	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	21	21	17	10	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	30 (30/30)[b]	30 (30/30)[b]	30 (30/30)[b]	30 (30/29)[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
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Pf and pan																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	30	30	30	30	30	30	28	29	10	10	10	10	10	10	10	10
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	30	30	30	30	29	28	30	29	10	10	10	10	10	10	10	10
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	30	30	30	30	30	26	29	21	10	10	10	10	10	10	10	10
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	30	30	30	30	30	30	27	25	10	10	10	10	10	10	10	10
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	30	30	30	30	8	0	0	2	10	10	10	10	10	10	10	10
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	30	30	30	30	9	15	13	25	10	10	10	10	10	10	10	10
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	30	30	30	30	29	30	30	29	10	10	10	10	10	10	10	10
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	19	27	22	28	16	28	23	29	9	10	10	10	9	10	10	10
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	30	30	30	30	30	8	23	22	10	10	10	10	10	10	10	10
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	30	30	30	30	5	17	15	28	10	10	10	10	10	10	10	10
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	30	30	30	30	14	8	21	21	10	10	10	10	10	10	10	10
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA

Table 6a *(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			
EGENS Malaria Pv/Pf Test Cassette	M A L - W 2 3 M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	30	30	30	30	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	30	30	30	29 (29)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	30	30	30	28 (28)	NA	NA	NA	NA	10	10	10	10	NA	NA	NA	NA
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	30	30	30	30	NA	NA	NA	NA	10	10	10	10
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	30	30	30	30	NA	NA	NA	NA	10	10	10	10
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	30 (30/30)[b]	30 (30/30)[b]	30 (30/28)[b]	30 (30/29)[b]	NA	NA	NA	NA	10 (10/10)[b]	10 (10/10)[b]	10 (10/10)[b]	10 (10/10)[b]	NA	NA	NA	NA

NA, not applicable

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

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

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

Table 6b: Heat stability testing results for 24 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]

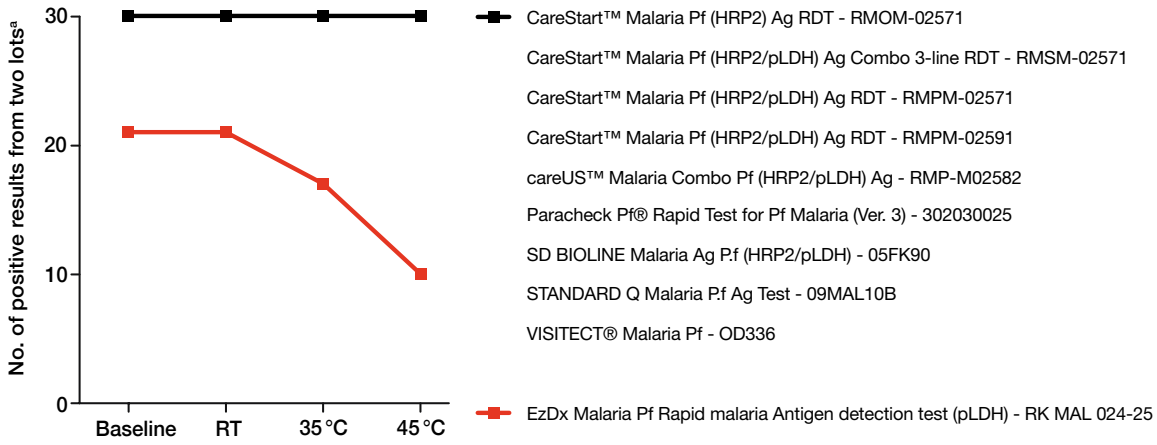
Product	Product code	Manufacturer	Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (Pan line)				Positive test results for *P. vivax* (Pv line)				Positive test results for *Plasmodium* (Pan line)			
			200 parasites/µL				200 parasites/µL				2000 parasites/µL				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																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	NA	NA	NA	NA	8	8	8	7 (7)	NA	NA	NA	NA	4	4	4	4
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	8	8	8	8	NA	NA	NA	NA	4	4	3 (3)	4	NA	NA	NA	NA
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	8	8	8	6	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	8	8	8	8	NA	NA	NA	NA	4	4	4	4
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	8	8	8	8	NA	NA	NA	NA	4	4	4	4	NA	NA	NA	NA

NA, not applicable

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

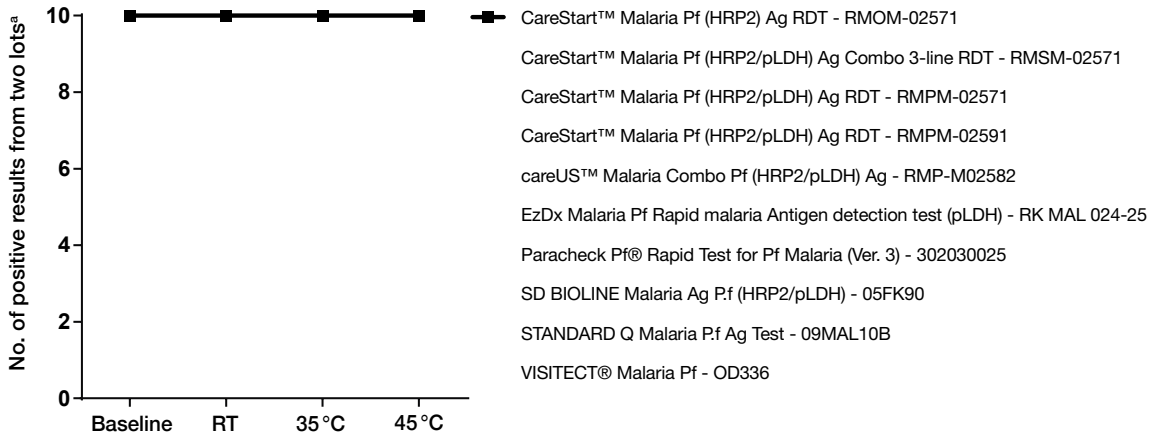
[a] Positive results presented in the table are based on stability of a positive reader 1 result

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



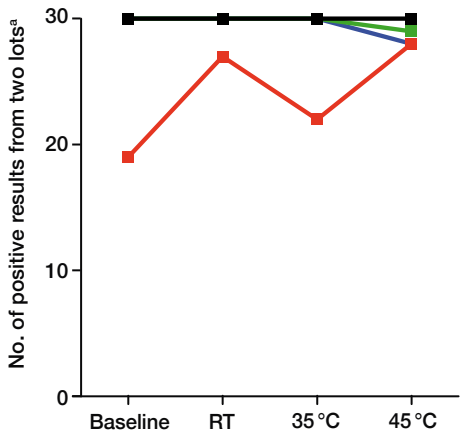
[a] Maximum score is 30 (15 tests x 2 lots)

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



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

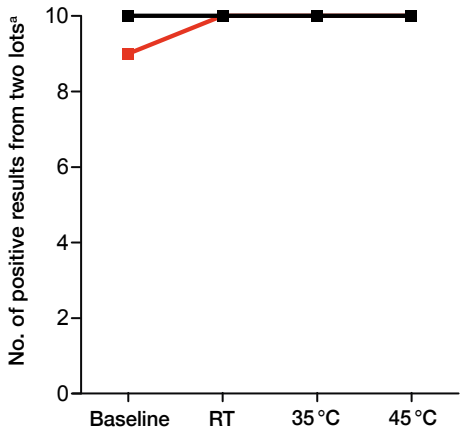
Figure 22: Heat stability of *P. falciparum*-specific test line in combination tests against a low-density *P. falciparum* sample (200 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
- CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02571
- CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
- CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-02571
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-02571
- CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT - RMWM-02571
- careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
- Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
- EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- First Response® Malaria Ag. P.f./P.v. Card test - PI19FRC25
- Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
- Malaria P.f./Pan Rapid Test Cassette - IMPN-402
- MERISCREEN Malaria Pf/Pan Ag - MHLRPD-02
- Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
- Parascreen® Rapid Test for Malaria Pan/Pf - 503030025
- SD BIOLINE Malaria Ag P.f/P.f/P.v - 05FK120
- STANDARD Q Malaria P.f / Pan Ag Test - 09MAL30B
- VISITECT® Malaria Pf/Pan - 0D326
- STANDARD Q Malaria P.f /P.v Ag Test - 09MAL20B
- VISITECT® Malaria Pf/Pv - 0D216
- MERISCREEN Malaria pLDH Ag - MVLRPD-02

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

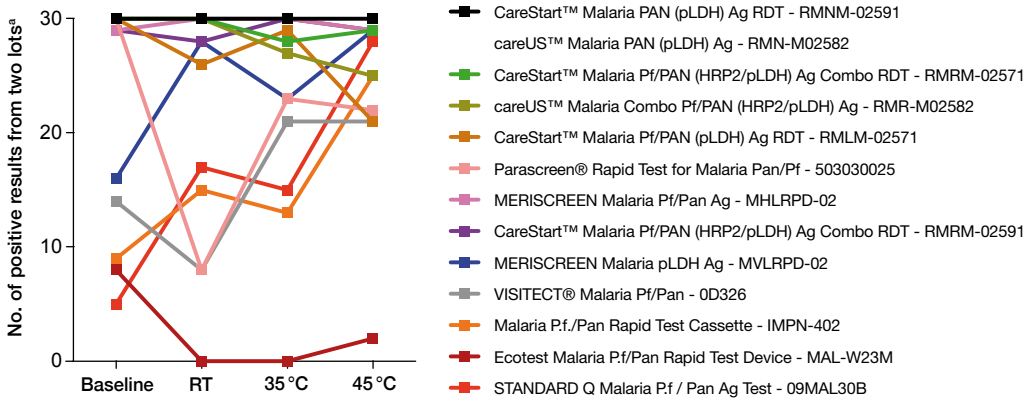
Figure 23: Heat stability of *P. falciparum*-specific test line in combination tests against a high-density *P. falciparum* sample (2000 parasites/µL). Positivity rate at baseline and after 60 days' incubation.



- Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
- CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02571
- CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
- CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-02571
- CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-02571
- CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT - RMWM-02571
- careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
- Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
- EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
- FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
- First Response® Malaria Ag. P.f./P.v. Card test - PI19FRC25
- Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
- Malaria P.f./Pan Rapid Test Cassette - IMPN-402
- MERISCREEN Malaria Pf/Pan Ag - MHLRPD-02
- Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
- Parascreen® Rapid Test for Malaria Pan/Pf - 503030025
- SD BIOLINE Malaria Ag P.f/P.f/P.v - 05FK120
- STANDARD Q Malaria P.f / Pan Ag Test - 09MAL30B
- STANDARD Q Malaria P.f /P.v Ag Test - 09MAL20B
- VISITECT® Malaria Pf/Pan - 0D326
- VISITECT® Malaria Pf/Pv - 0D216
- MERISCREEN Malaria pLDH Ag - MVLRPD-02

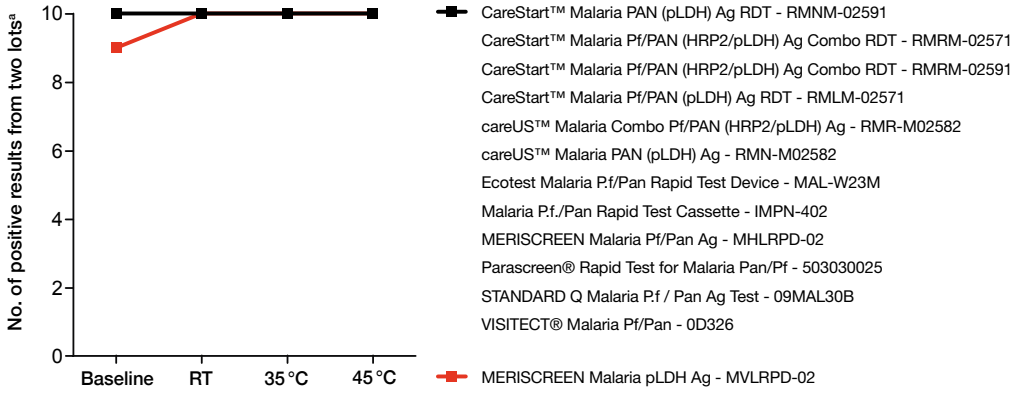
[a] Maximum score is 10 (5 tests x 2 lots)

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.



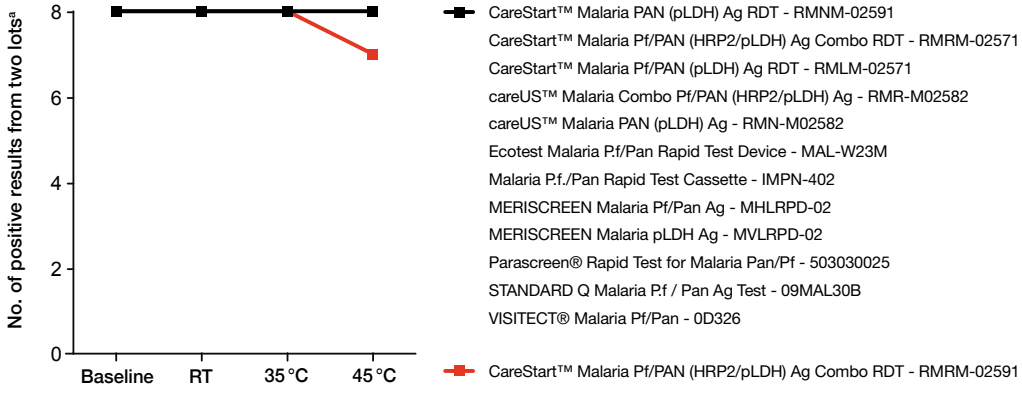
[a] Maximum score is 30 (15 tests x 2 lots)

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.



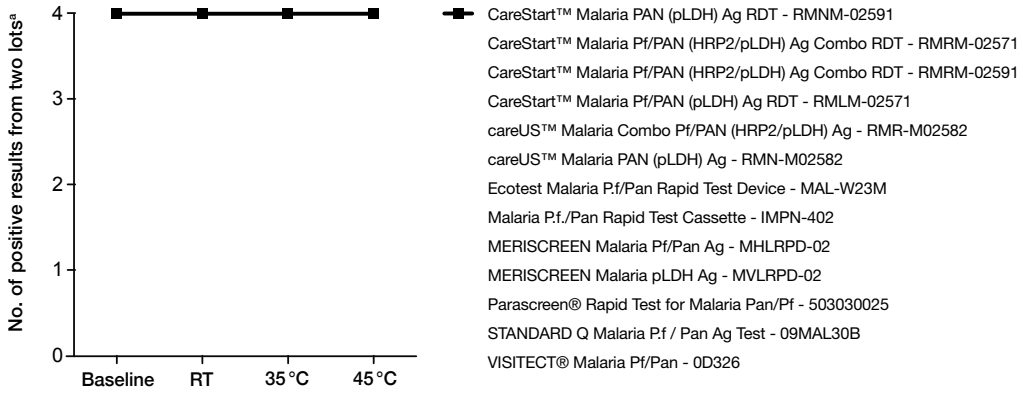
[a] Maximum score is 10 (5 tests x 2 lots)

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.



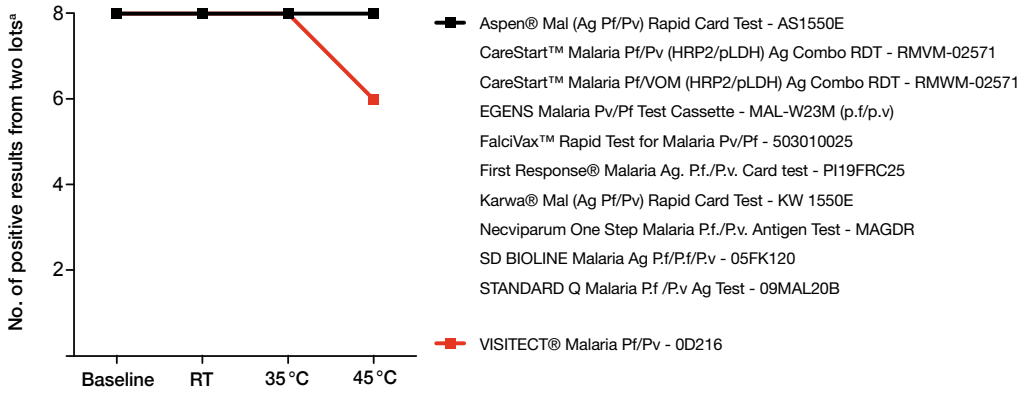
[a] Maximum score is 8 (4 tests x 2 lots)

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



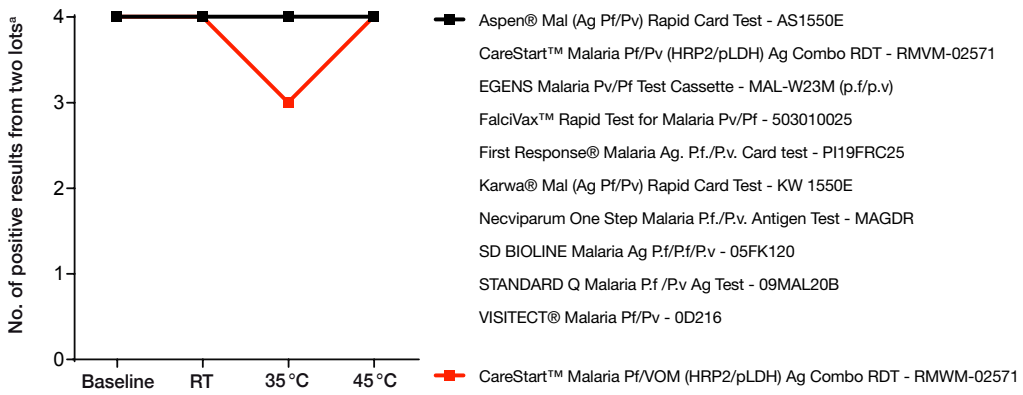
[a] Maximum score is 4 (2 tests x 2 lots)

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.



[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.



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

13.7 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 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).

13.8 Anomalies

In round 8, 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 8, all 35 products had at least least one anomaly.

Overall more anomalies were seen than in round 7, as 22 of 35 products showed at least one anomaly in > 5% of tests, and eight products showed an anomaly in > 25% of tests. Incomplete clearing and a red background (not obscuring test lines) were the most common anomalies, seen in 100% and 94% of products, respectively. Incomplete clearing in > 5% of tests was seen in 18 (53%) products. A red background obscuring the test lines, misplacement of the strip in the cassette and incomplete migration were the next most common anomalies, seen in 65%, 26% and 23% of products, respectively. A red background in 0.1–1.0% of tests was seen in 20 products, 12 products had a red background in > 1.0% of tests and three products had a red background in >20% of tests. A red background obscuring the test lines was seen in 0.1-1.0% of tests in 23 products and 0.0% in 12 products.

13.9 Inter-lot variation

Less consistency between lots was seen than in round 7, especially for *P. vivax* samples. The average difference in positivity rate was 2.0 percentage points (range, 0.0–6.0) for low-density *P. falciparum* samples, with 100 products tested per lot, and 2.4 percentage points (range, 0.0–14.3) for low-density *P. vivax* samples, with 35 products tested per lot.

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

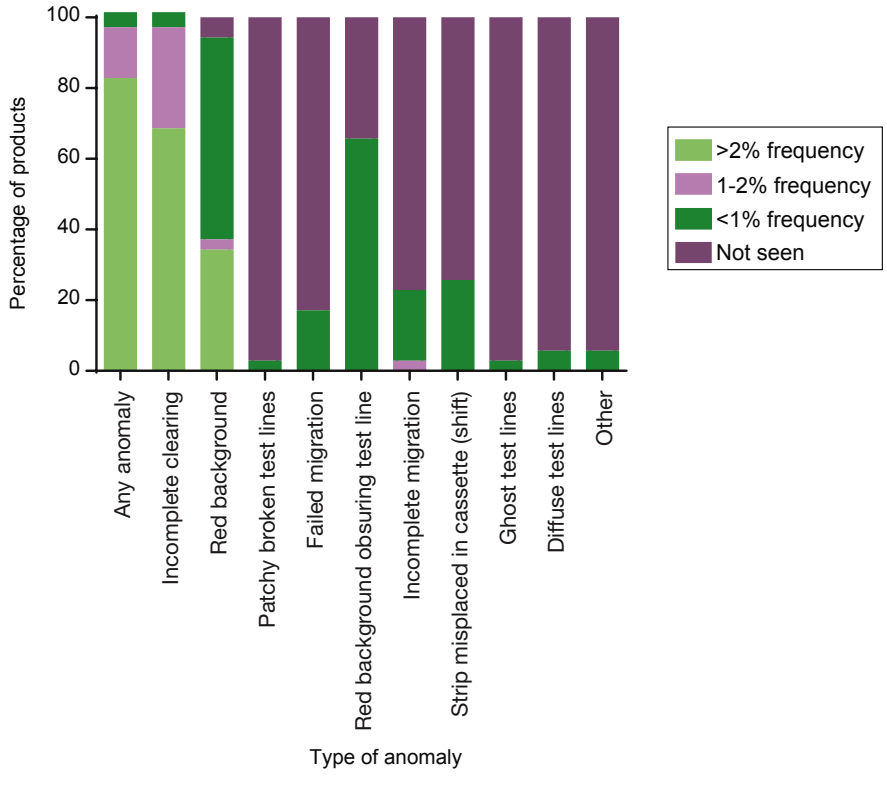


Table 7: Ease-of-use description of 35 malaria RDTs included in round 8

Product	Product code	Manufacturer	Blood safety[a]				Instruction quality[b]				*Combined score* (max. 5)	Number of timed steps	Total time to result	Desiccant with color indicator (yes/no)	Buffer					Blood transfer device	Format	Language of instruction	Items included in RDT box[c]
			Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result (1)	Diagram of result & method (2)	Score (max.2)					Container does not puncture	Does not flow freely	Insufficient volume	Empty (bottle or vial)	Discoloured				
Pf only																							
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio Inc.	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	1	0	1	**2**			2	**2**	**4**	1	20	yes	X					pipette	cassette	English	Desiccant
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	1	0	0	**1**			2	**2**	**3**	1	20	yes						pipette	cassette	English	Desiccant
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	1	0	1	**2**			2	**2**	**4**	1	20	yes						loop	cassette	English	Desiccant, loop
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	1	0	0	**1**			2	**2**	**3**	1	15	yes	X					inverted cup	cassette	English, French, Spanish, Portuguese	Desiccant
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	1	NA	0	**1**			2	**2**	**3**	1	15	yes	X					inverted cup	cassette	English	Desiccant
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	1	0	0	**1**		1		**1**	**2**	1	20	yes						inverted cup	cassette	English	Desiccant, inverted cup
Pf and pan																							
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	1	0	0	**1**			2	**2**	**3**	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	1	0	1	**2**			2	**2**	**4**	1	20	yes	X					pipette	cassette	English	Desiccant
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	1	1	0	**2**			2	**2**	**4**	1	15	yes	X					pipette	cassette	English	Desiccant
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	1	NA	0	**1**			2	**2**	**3**	1	10	no	X					pipette	cassette	English	Desiccant
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	1	0	0	**1**		1		**1**	**2**	1	20	no						loop	cassette	English	Desiccant
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	1	0	0	**1**		1		**1**	**2**	1	20	no						loop	cassette	English	Desiccant
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	1	0	1	**2**			2	**2**	**4**	1	20	yes						loop	cassette	English	Desiccant, loop
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	1	NA	0	**1**			2	**2**	**3**	1	15	yes	X					inverted cup	cassette	English	Desiccant
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	1	0	0	**1**		1		**1**	**2**	1	20	yes						inverted cup	cassette	English	Desiccant, inverted cup

Table 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 color indicator (yes/no)	Buffer					Blood transfer device	Format	Language of instruction	Items included in RDT box[c]
			Mixing wells involved	Retractable needle	Strip Exposed	Score (max. 3)	No diagram	Diagram of result (1)	Diagram of result & method (2)	Score (max.2)					Container does not puncture	Does not flow freely	Insufficient volume	Empty (bottle or vial)	Discoloured				
Pf and Pv/Pvom																							
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	1	0	0	1			2	2	3	1	20	yes						loop	cassette	English	Desiccant
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	1	0	0	1			2	2	3	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	1	0	0	1			2	2	3	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
EGENS Malaria Pv/Pf Test Cassette	M A L - W 2 3 M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	1	1	1	3			2	2	5	1	20	no	X					pipette	cassette	English	Desiccant, pipette
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1	0	1	2			2	2	4	1	20	yes						loop	cassette	English	Desiccant, loop
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	1	0	1	2			2	2	4	1	20	yes	X					inverted cup	cassette	English	Desiccant, inverted cup
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	1	0	0	1			2	2	3	1	20	yes						loop	cassette	English	Desiccant
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	1	0	0	1			2	2	3	1	20	yes						pipette	cassette	English	Desiccant, pipette
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	1	NA	0	1			2	2	3	1	15	yes	X					inverted cup	cassette	English	Desiccant
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	1	0	0	1		1		1	2	1	20	yes						inverted cup	cassette	English	Desiccant, inverted cup
Pan only																							
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	1	0	0	1			2	2	3	1	20	no	X					pipette	cassette	English, French, Spanish, Portuguese	Desiccant
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	1	0	1	2			2	2	4	1	20	yes	X					pipette	cassette	English	Desiccant
Pf, Pf and Pv																							
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	1	0	0	1			2	2	3	1	15	yes	X					inverted cup	cassette	English, French, Spanish, Portuguese	Desiccant

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 what 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 1 and phase 2

Product	Product code	Manufacturer	Percentage of tests with at least one anomaly	Percentage of tests with specified anomaly (n=1330)									
				Red background	Red background obsuring test line(s)	Incomplete clearing	Incomplete migration	Failed migration	Strip misplaced in cassette (shift)	Ghost test lines	Diffuse test lines	Patchy broken test line	Other
Pf only													
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	1.8	0.3	0.2	1.3	0.0	0.1	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio Inc.	2.9	0.9	0.0	1.9	0.0	0.0	0.1	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	0.6	0.4	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	1.3	0.2	0.0	1.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	2.7	0.8	0.4	1.3	0.1	0.0	0.0	0.0	0.2	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II)[a]	RK MAL 025-25	Advy Chemical Pvt. Ltd.	5.8	2.5	0.8	1.7	0.8	0.0	0.0	0.0	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	9.0	3.0	0.1	5.7	0.0	0.0	0.3	0.0	0.0	0.0	0.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	4.4	0.0	0.0	4.3	0.1	0.0	0.1	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	4.0	0.5	0.2	3.2	0.0	0.0	0.0	0.0	0.0	0.1	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	4.8	0.2	0.1	4.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	45.2	23.0	0.2	21.8	0.1	0.1	0.0	0.0	0.0	0.0	0.0
Pf and pan													
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	2.4	0.4	0.2	1.8	0.0	0.0	0.1	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	1.7	0.2	0.0	1.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	5.9	2.6	0.1	3.2	0.0	0.0	0.1	0.0	0.1	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	1.9	0.0	0.0	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	68.3	53.8	0.0	14.4	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	70.4	49.2	0.5	20.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	11.7	0.9	0.2	10.3	0.1	0.0	0.2	0.0	0.0	0.0	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	6.6	0.7	0.3	5.6	0.0	0.0	0.1	0.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	1.9	0.1	0.0	1.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	10.7	0.4	0.1	10.2	0.0	0.1	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	40.2	16.2	0.5	23.2	0.1	0.2	0.0	0.0	0.0	0.0	0.0
Pf and Pv/Pvom													
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	27.5	6.8	0.4	20.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	2.0	0.2	0.0	1.9	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	2.4	0.2	0.0	2.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	30.5	13.5	0.3	16.6	0.0	0.1	0.1	0.0	0.0	0.0	0.0

Table 8 *(continued)*

Product	Product code	Manufacturer	Percentage of tests with at least one anomaly	Percentage of tests with specified anomaly (n=1330)									
				Red background	Red background obsuring test line(s)	Incomplete clearing	Incomplete migration	Failed migration	Strip misplaced in cassette (shift)	Ghost test lines	Diffuse test lines	Patchy broken test line	Other
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	4.8	0.7	0.0	4.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	8.9	0.5	0.1	8.0	0.1	0.0	0.0	0.2	0.0	0.0	0.1
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	23.7	8.3	0.0	15.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	17.7	5.0	0.8	10.8	1.1	0.0	0.0	0.0	0.0	0.0	0.1
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	6.8	0.3	0.1	6.2	0.0	0.1	0.2	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	27.6	6.7	0.2	20.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pan only													
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	6.6	0.9	0.1	5.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	7.3	1.7	0.2	5.5	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf, Pf and Pv													
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	4.6	0.6	0.2	3.8	0.0	0.0	0.0	0.0	0.0	0.0	0.0

[a] Product had high false positive rates on 20 clean negative samples in phase 1. Therefore, it was not included in phase 2

14. Testing of RDTs against HRP2-negative *P. falciparum* samples

14.1 Panel detection score and positivity rate

Round 8 was launched at a time when several new reports were published on false-negative results for *pfhrp2*-deleted parasites. Many manufacturers responded by submitting RDTs that target Pf-LDH either exclusively or in combination with HRP2. The WHO-FIND RDT Evaluation Steering Group not only screened these RDTs against HRP2-expressing *P. falciparum* samples but also recommended inclusion of an ad-hoc panel of well-characterized clinical and cultured *pfhrp2*-deleted *P. falciparum* samples to guide future WHO recommendations and policy on RDT procurement.

All RDTs were assessed against the panel that contained only low-parasite-density samples or samples with antigen concentrations comparable to 200 parasites/µL, and products were grouped according to the types of antigens they detected. Nine products were designed to detect *P. falciparum* with Pf-LDH alone or in combination and should therefore have identified HRP2-negative samples; two products were designed to detect *P. falciparum* with pan-LDH only and should therefore have detected HRP2-negative samples; and four products were designed to detect *P. falciparum* with HRP2 only and should therefore have shown decreased performance against HRP2-negative samples, particularly against dual *pfhrp2*- and *pfhrp3*-deleted samples. Nineteen products were designed to detect *P. falciparum* with HRP2 only but also had a test line for pan-LDH, Pv-LDH or vom-LDH; therefore, while the HRP2 test line should not have detected *P. falciparum*, the pan line might have among products with a pan line.

Overall, the PDS of products varied considerably, four having a PDS of 0% and one having the highest PDS of 90% (Table 9). Of the nine products designed to detect *P. falciparum* with Pf-LDH alone or in combination, three products tested for *P. falciparum* with HRP2 and Pf-LDH on the same test line had PDS values of 17.5%, 22.5% and 60%. The PDS of products with HRP2 and Pf-LDH on different test lines had PDS values of 12.5%, 20.0% and 32.5%; however, the PDS based only on the HRP2 test line was 0.0% for all products. The PDS of the three products that tested for *P. falciparum* with Pf-LDH alone, without HRP2, was 0.0–12.5%. The two pan-LDH-only products had PDS values of 85% and 90%. The PDS of the four products designed to detect *P. falciparum* with HRP2 alone ranged from 15.0% to 45%, with a median of 27.5%, while the PDS of the 19 products designed to test for *P. falciparum* with HRP2 only but that also had a non-*P. falciparum*-LDH line ranged from 0% to 35% (median, 12.5%).

Most products had lower PDS and positivity rates against the HRP2-negative panel than the phase-2 wild-type *P. falciparum* panel (Figs 31 and 32). This was the case even for products designed to detect *P. falciparum* with pf-LDH and not HRP2. Only the two pan-LDH RDTs maintained high panel detection scores of 85% and 90%, and both had a PDS values of 98% in phase 2. As expected, the HRP2-based RDTs failed to detect dually deleted parasites; however, some detected *pfhrp2*-negative/p*fhrp3*-positive samples, and many picked up both single- and dual-deleted samples on the pan-LDH line in combination tests (Fig. 33). The latter, however, were categorized as false-positives for non-*P.falciparum* infections.

The false-positive rate of 22 products for non-*P. falciparum* infections ranged from 0% to 59.4%; seven products had a rate of 0%, and eight products had a false-positive rate > 30%. Invalid tests were found for only one product.

14.2 Band intensity

The band intensities for *P. falciparum* detecting bands against HRP2-negative samples were weak with a maximum intensity of 2 (Table A4.20). The mean band intensity of positive Pf-LDH detecting test bands was 1.20 indicating most positive tests had faint test bands. The mean Pf-LDH band intensities for individual products ranged from 1.00 to 1.33. The two pan-LDH RDTs had the highest mean band intensity at 1.61. The mean band intensities of HRP2-detecting test bands were 1.25 and 1.14 for HRP2-only and HRP2 combination RDTs, respectively. For combination products the band intensies of the *P. falciparum* detecting test bands were similar to the pan-LDH test bands; 1.20 for both bands in Pf-LDH detecting RDTs and 1.14 compared to 1.12 for RDTs using HRP2 in combination with pan-LDH.

14.3 Inter-lot variation

The difference in positivity rate between lots against HRP2-negative samples was higher than that for wild-type phase 2 *P. falciparum* samples, with an average of 6.3 percentage points difference betweet lots against *pfhrp2-/pfhrp3-* (range, 0.0–27.8)(Table A4.19). The difference was highest among products that test for *P. falciparum* alone or in combination with another antigen, mainly because the PDS of HRP2-based products was very low, usually 0%, in both tests. The difference for *pfhrp2–/pfhrp3+* samples was greater, with an average of 22.2 percentage points difference (range, 4.5–38.6%).

Table 9: Summary of performance of 34 malaria RDTs against HRP2-negative *P. falciparum* samples[a]

Product	Product code	Manufacturer	Panel Detection Score[b] (n=40)	Positivity rate[c] (n=160)	False positive rates (%)	Invalid rate (%) (n=160)
					False positive non-Pf infection[d] (n=160)	
Detect Pf using pf-pLDH alone or in combination						
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio, Inc.	12.5 (0/12.5)[e]	61.3	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio, Inc.	60.0	85.0	NA	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	17.5	62.5	NA	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio, Inc.	0.0	12.5	43.8	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	22.5	62.5	NA	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	12.5	56.9	NA	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt Ltd.	10.0	50.0	18.1	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	32.5 (0/32.5)[e]	68.1	NA	0.0
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	20.0 (0/20)[e]	55.6	0.0	0.0
Detect Pf using pan-pLDH only						
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	90.0	96.9	NA	0.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	85.0	94.4	NA	0.0
Detect Pf using HRP2 only (Pf only tests)						
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio, Inc.	22.5	35.0	NA	0.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	15.0	40.6	NA	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	32.5	41.9	NA	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	45.0	56.3	NA	0.0
Detect Pf using HRP2 only (Pf/pan, Pf/Pv and Pf/VOM tests)						
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	ASPEN LABORATORIES PVT.LTD	32.5	43.1	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio, Inc.	7.5	13.8	55.6	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	12.5	19.4	59.4	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio, Inc.	10.0	14.4	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio, Inc.	10.0	10.0	1.3	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	12.5	19.4	53.8	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	2.5	5.6	13.8	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	25.0	36.3	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	3.1	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	12.5	23.1	0.0	0.0

Table 9: Summary of performance of 34 malaria RDTs against HRP2-negative *P. falciparum* samples[a] *(continued)*

Product	Product code	Manufacturer	Panel Detection Score[b] (n=40)	Positivity rate[c] (n=160)	False positive rates (%)	Invalid rate (%) (n=160)
					False positive non-Pf infection[d] (n=160)	
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises pvt ltd	35.0	43.1	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	20.6	12.5	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt Ltd.	7.5	23.1	51.3	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	32.5	45.9 (159)	0.6 (159)	0.6
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.6	50.6	0.0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	25.0	40.6	0.6	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	32.5	41.9	28.1	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	35.0	50.0	31.3	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	20.0	46.9	40.6	0.0

NA, not applicable

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

[a] 18 samples were HRP2-/HRP3 - and 22 samples were HRP2-/HRP3+ and included 7 wild-type (200 parasites/µL) and 33 samples dervied from 8 culture isolates diluted to antigen concentration range of 200 parasites/µL

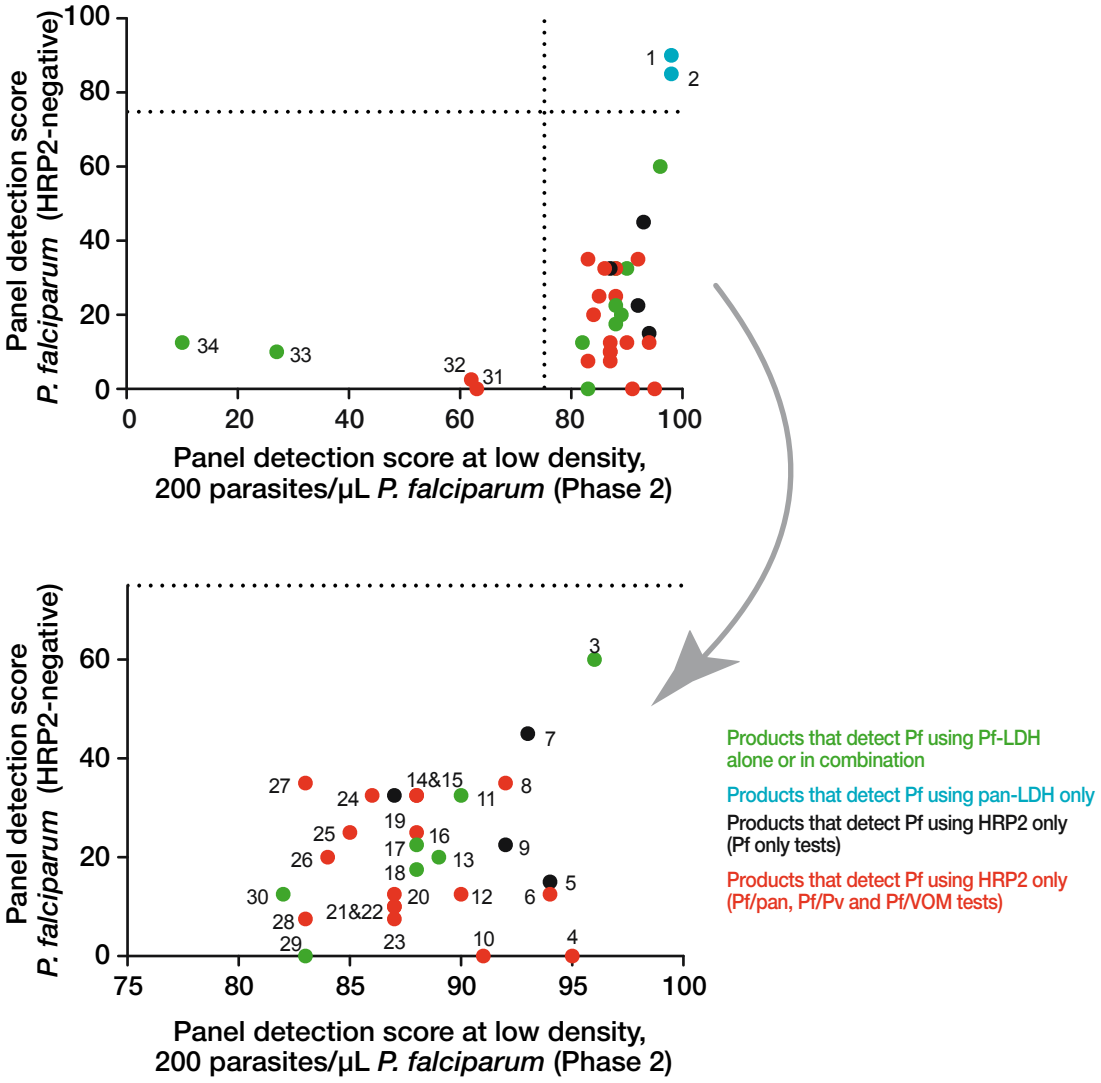
[b] A sample is considered detected only if all RDTs from both lots read by the first technician, at minimum specified reading time, are positive

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

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

[e] Product PDS shown along with PDS for HRP2 band and Pf-LDH band, respectively

Figure 31: Panel detection score of RDTs against *P. falciparum* HRP2 negative panel[a] versus panel detection score for Phase–2 *P. falciparum* 200 parasites/µL panel[b]

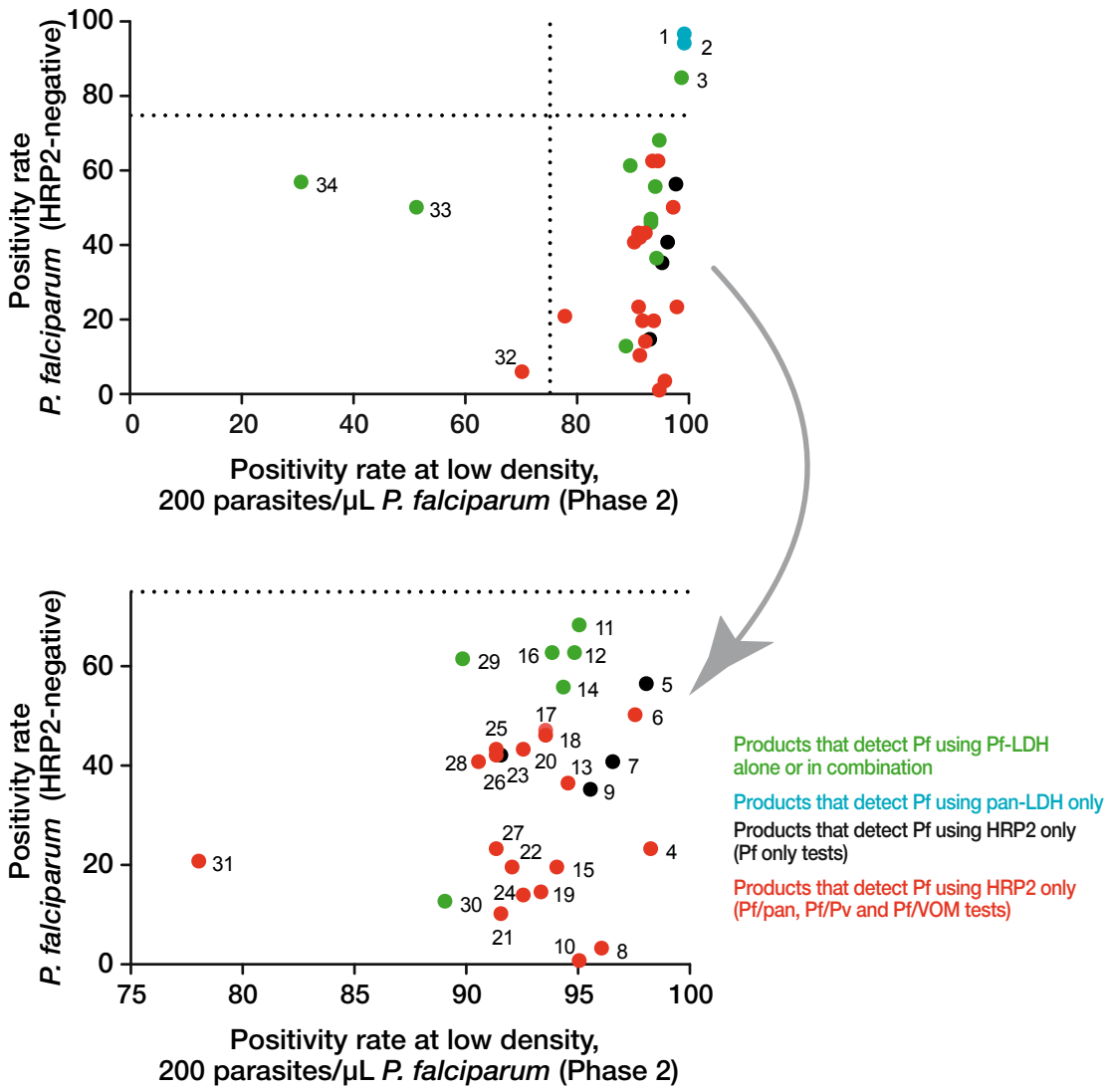


1 CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM-02591
2 careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
3 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02571
4 FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
5 Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3) - 302030025
6 First Response® Malaria Ag. P.f./P.v. Card test - PI19FRC25
7 VISITECT® Malaria Pf - 0D336
8 VISITECT® Malaria Pf/Pan - 0D326
9 CareStart™ Malaria Pf (HRP2) Ag RDT - RMOM-02571
10 Parascreen® Rapid Test for Malaria Pan/Pf - 503030025
11 SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - 05FK90
12 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
13 SD BIOLINE Malaria Ag P.f/P.f/P.v - 05FK120
14 Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
15 STANDARD Q Malaria P.f/Pan Ag Test - 09MAL30B
16 EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
17 careUS™ Malaria Combo Pf (HRP2/pLDH) Ag - RMP-M02582
18 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02591
19 STANDARD Q Malaria P.f Ag Test - 09MAL10B
20 careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
21 CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-02571
22 CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT - RMWM-02571
23 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02571
24 Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
25 STANDARD Q Malaria P.f/P.v Ag Test - 09MAL20B
26 VISITECT® Malaria Pf/Pv - 0D216
27 Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
28 MERISCREEN Malaria Pf/Pan Ag - MHLRPD-02
29 CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-02571
30 CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - RMSM-02571
31 Malaria P.f./Pan Rapid Test Cassette - IMPN-402
32 Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
33 MERISCREEN Malaria pLDH Ag - MVLRPD-02
34 EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH) - RK MAL 024-25

[a] HRP2-negative panel consisted of 40 clinical and cultured blood samples containing *P. falciparum*. See table AS1.6 for antigen concentrations

[b] Phase-2 panel consisted of 100 clinical blood samples containing wild-type *P. falciparum*.

Figure 32: Positivity rate of RDTs against *P. falciparum* HRP2 negative panel[a] versus positivity rate for Phase-2 *P. falciparum* 200 parasites/µL panel[b]

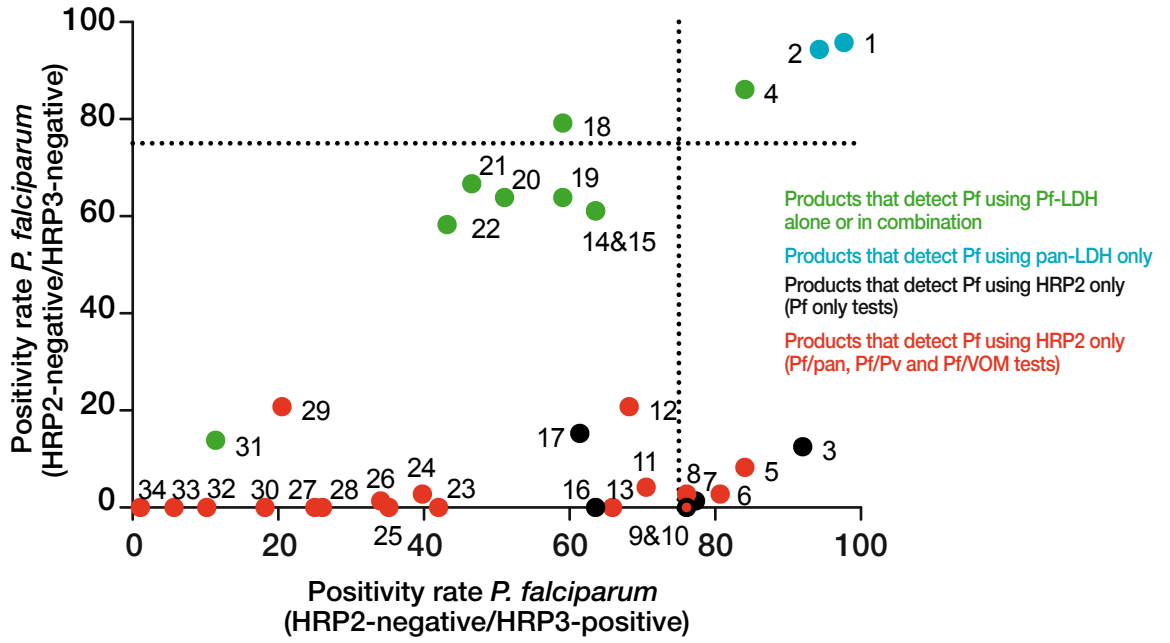


1 CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM-02591
2 careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
3 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02571
4 First Response® Malaria Ag. P.f./P.v. Card test - PI19FRC25
5 VISITECT® Malaria Pf - 0D336
6 VISITECT® Malaria Pf/Pan - 0D326
7 Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3) - 302030025
8 FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
9 CareStart™ Malaria Pf (HRP2) Ag RDT - RMOM-02571
10 Parascreen® Rapid Test for Malaria Pan/Pf - 503030025
11 SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - 05FK90
12 careUS™ Malaria Combo Pf (HRP2/pLDH) Ag - RMP-M02582
13 EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
14 SD BIOLINE Malaria Ag P.f/P.f/P.v - 05FK120
15 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
16 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02591
17 VISITECT® Malaria Pf/Pv - 0D216
18 Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
19 CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-02571
20 Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
21 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02571
22 careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
23 STANDARD Q Malaria P.f Ag Test - 09MAL10B
24 CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT - RMWM-02571
25 Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
26 STANDARD Q Malaria P.f/Pan Ag Test - 09MAL30B
27 MERISCREEN Malaria Pf/Pan Ag - MHLRPD-02
28 STANDARD Q Malaria P.f/P.v Ag Test - 09MAL20B
29 CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - RMSM-02571
30 CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-02571
31 Malaria P.f./Pan Rapid Test Cassette - IMPN-402
32 Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
33 MERISCREEN Malaria pLDH Ag - MVLRPD-02
34 EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH) - RK MAL 024-25

[a] HRP2-negative panel consisted of 40 clinical and cultured blood samples containing *P. falciparum*. See table AS1.6 for antigen concentrations

[b] Phase-2 panel consisted of 100 clinical blood samples containing wild-type *P. falciparum*.

Figure 33: Positivity rate of RDTs against *P. falciparum* HRP2/HRP3 dual- negative panel[a] versus positivity rate for *P. falciparum* HRP2-negative/HRP3 positive panel[b]



1 CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM-02591
2 careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
3 VISITECT® Malaria Pf - 0D336
4 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02571
5 VISITECT® Malaria Pf/Pan - 0D326
6 Necviparum One Step Malaria P.f./P.v. Antigen Test - MAGDR
7 Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
8 Karwa® Mal (Ag Pf/Pv) Rapid Card Test - KW 1550E
9 STANDARD Q Malaria P.f Ag Test - 09MAL10B
10 STANDARD Q Malaria P.f/Pan Ag Test - 09MAL30B
11 STANDARD Q Malaria P.f/P.v Ag Test - 09MAL20B
12 VISITECT® Malaria Pf/Pv - 0D216
13 EGENS Malaria Pv/Pf Test Cassette - MAL-W23M (p.f/p.v)
14 CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT - RMPM-02591
15 careUS™ Malaria Combo Pf (HRP2/pLDH) Ag - RMP-M02582
16 CareStart™ Malaria Pf (HRP2) Ag RDT - RMOM-02571
17 Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3) - 302030025
18 SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - 05FK90
19 CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - RMSM-02571
20 EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH) - RK MAL 024-25
21 SD BIOLINE Malaria Ag P.f/P.f/P.v - 05FK120
22 MERISCREEN Malaria pLDH Ag - MVLRPD-02
23 First Response® Malaria Ag. P.f./P.v. Card test - PI19FRC25
24 MERISCREEN Malaria Pf/Pan Ag - MHLRPD-02
25 careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag - RMR-M02582
26 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02591
27 CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT - RMVM-02571
28 CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT - RMRM-02571
29 Malaria P.f./Pan Rapid Test Cassette - IMPN-402
30 CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT - RMWM-02571
31 CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-02571
32 Ecotest Malaria P.f/Pan Rapid Test Device - MAL-W23M
33 FalciVax™ Rapid Test for Malaria Pv/Pf - 503010025
34 Parascreen® Rapid Test for Malaria Pan/Pf - 503030025

[a] The P. *falciparum* HRP2-negative/HRP3 negative panel consisted of 11 cultured blood samples and 7 clinical samples
b The *P. falciparum* HRP2-negative/HRP3-positive panel consisted of 22 cultured *P. falciparum* blood samples.

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. In order that malaria RDTs 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 and to support WHO IVD prequalification. The panels used ensured successful discrimination among 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. Most of the RDTs, however, failed to meet WHO PDS performance requirements for detection of *pfhrp2*-negative *P. falciparum*.

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 among 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 (*10*).

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

(i) The performance of different lots or batches of the same product may vary. Variation in lot performance is an issue for all diagnostics; therefore, the results found in the evaluation may not predict the results for subsequent RDT lots. It is important to test lots before their distribution in the field to ensure that the expected performance is maintained (section 16.3).

(ii) In clinical settings, the parasite density of patients varies widely, 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 be an underestimate of 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 among the better-performing RDTs in this evaluation are unlikely to result in noticeable differences in clinical sensitivity. Other issues, such as the required storage conditions, stability, cost, experience and the training of the intended users, ease of use (Annex S2) and manufacturing capacity, may be equally important in test selection. Consideration of the parasite density 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 reliably 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, including the Democratic Republic of the Congo *(16)*, Eritrea *(17)* and India *(13)*, and in South America *(12)* do not express HRP2 antigens because of gene deletions that result in false negatives (*12*). Before round 8, the reactivity of the non-HRP2, *P. falciparum*-specific test lines against *P. falciparum* (HRP2-containing) samples in phases 1 and 2 was considered the best predictor of how well these RDTs would detect *pfhrp2*-negative parasites. Assessment in round 8 of RDTs against a panel of *pfhrp2* +/– *pfhrp3*-deleted clinical and cultured samples revealed, however, that most RDTs did not react as would have been predicted. More investigations are

required to determine the discrepancies in performance and to assess whether the discrepancies disappear at higher parasite or antigen concentrations.

(iv) The conditions under which RDTs are transported and stored can alter their sensitivity in the field. The tests evaluated in round 8 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 (*39–41*).

(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 necessary to ensure translation of the technical proficiency of a product into accurate diagnoses in the field (*42–44*).

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 for 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 virus-infected 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. A secondary analysis of data generated by six rounds of the WHO malaria RDT product testing programme was recently conducted to investigate the frequency of false-positive RDT results against several infectious agents and immunological factors *(45)*.

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-LDH 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 HRP2 test line-positive alone or in combination with the pan-LDH 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 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 ensure adherence to the manufacturer's instructions for use (Annex 2) and to understand that, for combination HRP2/pan-LDH tests, a HRP2 test line-positive alone may well be attributable to the poor reactivity of pan-LDH lines and not to persistent HRP2 antigenaemia.

15.4 Heat (thermal) stability

The RDTs evaluated were held for two months at room temperature (21–24°C) and at 35°C and 45°C at 75% humidity and were 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 coolers 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. The packaging should, if in good condition, protect the contents from exposure to high humidity during storage. 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 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-LDH lines were highly stable at all temperatures and times tested. In most products, Pv-LDH lines were also highly stable. These results for *P. vivax* are an improvement over those in round 7.

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 part of their storage time and the likelihood of greater susceptibility to degradation during short exposure to much higher temperatures, such as during transport (*39, 40*).

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 (*42*). 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. No dipstick tests were evaluated in round 8.

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 differ widely in design and accuracy (*37*). 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 *(11, 42)*. Annex S2 provides guidance on assessing ease-of-use in the field (Table AS3.1).

15.6 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 thousands of 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.

15.7 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 the appropriate standard. This can be facilitated by WHO through two WHO-recognized lot-testing facilities (section 16.3).

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 *P. falciparum* panels that are subsets of the phase-1 panel used in this evaluation are available through the WHO malaria specimen bank[1], as reference standards against which manufacturers can set their lot-release criteria.

[1] http://www.who.int/malaria/areas/diagnosis/rapid-diagnostic-tests/malaria_specimen_bank/en/ (accessed 23 August 2018).

15.8 RDT performance against the HRP2-negative panel

In previous rounds of testing, the reactivity of the non-HRP2 *P. falciparum*-specific test lines against phases 1 and 2 *P. falciparum* (HRP2-containing) samples was considered the best predictor of how well these RDTs would detect *pfhrp2*-negative parasites, and this was the basis for WHO interim recommendations on RDT procurement in areas with prevalent *pfhrp2*-deletions *(48)*. This approach did not, however, allow predictions of how RDTs with HRP2 and non-HRP2 target antigens on the same test line would perform or the extent of RDT cross-reactivity between HRP2 and HRP3 and could not account for other characteristics of *pfhrp2/3*-negative *P. falciparum* strains that may affect their performance. Therefore, a *pfhrp2/3*-negative panel was included ad hoc in round 8. When the PDS and positivity rates of non-HRP2 *P. falciparum*-specific tests and test lines in phase 2 and the *pfhrp2/3*-negative panel were compared, the performance of the latter was significantly lower (Figs 31, 32). Only the two products that tested for pan-LDH alone met the WHO PDS performance criteria against HRP2-negative *P. falciparum.* This discrepancy is not likely to be explained by the difference in the pLDH antigen concentrations in the two panels; the median pLDH concentrations in the HRP2-negative and phase-2 panels were 9.85 ng/mL (interquartile range, 5.48–20.65 ng/mL) and 13.59 (7.20–21.51 ng/mL), respectively, and there was no significant difference in the mean pLDH concentrations of the single-deleted parasites, double-deleted parasites (data not presented) and the phase-2 parasites (p = 0.165) (Table AS1.6); however, the RDTs were nearly one year older when they were tested against the HRP2-negative panel, and even minor deterioration in sensitivity could result in a decrease in the limits of detection of several RDTs. When the nine Pf-LDH detecting RDTs were tested with clinical and cultured double deleted *pfhrp2/3*samples with an antigen concentration in the range of 2000 parasites/µL, eight had 100% positivity (PDS=100) while one RDT detected *P. falciparum* in only 61.1% of the samples[1] (manuscript submitted for publication). Most of the samples in the HRP2-negative panel were derived from three culture isolates (only 7/40 samples were clincial blood samples), and, although RDT performance against double-deleted culture isolates and wild-type/clinical samples did not differ, there may be as yet unelucidated inherent differences between HRP2-negative and HRP2-expressing *P. falciparum* parasites that affect RDT reactivity with Pf-LDH antibodies. Alternatively, HRP2 might inadvertently react with the Pf-LDH test bands of some products, which would increase their performance in phase 2. The results confirmed field reports of RDT cross-reactivity between HRP2 and HRP3 in single-deleted parasites, but there is wide variation among products (Fig. 33). Similarly, there was wide variation (range, 12.5–59.4%; median, 31.3%) in false-positivity for non-*P. falciparum* infection rates based on reactivity with pan-LDH test lines on combination tests. This reflects the variable sensitivity of pan-LDH test lines (section 15.4) and variable cross-reactivity of HRP3 with HRP2 test lines.

Despite the small, geographically restricted panel, the results suggest that pan-LDH RDTs are the best option for the combined detection of HRP2-expressing and non-HRP2-expressing *P. falciparum* (and non-*P.falciparum* species). In places where case management requires an RDT that can distinguish between *P. falciparum* and non- *P.falciparum* or *P. vivax* infection, preliminary data from round 8 suggest that, at higher parasite density (2000 parasites/µL) and pLDH antigen concentration, Pf-LDH RDTs perform well. Nevertheless, low-density infections might be missed, and safeguards should be put in place when feasible. The results of this first assessment against HRP2/HRP3-negative *P. falciparum* samples indicate that the evaluation should be broadened in terms of size, characteristics and geographical diversity.

When positive results on the *P. falciparum*-detecting test bands were obtained against HRP2-negative samples, the band intensities were generally weak (1–2); only three products returned one result (1/160) with a band intensity of 3, and none returned a band intensity of 4 (Table A4.20). This is in stark contrast to the appearance of *P. falciparum*-detecting test bands against the phase 2 wild-type panel (Table A4.2).

Inter-lot variation against the HRP2-negative panel was much higher than against the phase-2 *P. falciparum* panel and was greater for *hrp2*–negative/*hrp3*-positive samples than for *hrp2*–negative/*hrp3*–negative samples. The variation is probably due to the fact that the parasite density was at the limit of detection of the RDTs. As the number of positive readings against *hrp2*–negative/*hrp3*-positive samples was generally higher than that against *hrp2*–negative/*hrp3*–negative because of the cross-reactivity of the HRP3 protein with the HRP2 antibody, the inter-lot variation was reduced.

15.9 Selecting RDTs: target antigens, species and sensitivity

15.9.1 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. In some tests, differences in pLDH sequences between species 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.

[1] Michelle Gatton, Alisha Chaudhy, Jeff Glenn, Scott Wilson, Yong Ah, Amy Kong, Peter Chiodini, Sandra Incardona, Qin Cheng, Michael Aidoo, Jane Cunningham. Comparison of performance of malaria rapid diagnostic tests (RDTs) against wild type and HRP2-negative *Plasmodium falciparum*. Manuscript submitted for publication

In choosing an RDT, account should be taken of the target antigen: HRP2-detecting RDTs should not be used exclusively in areas where false-negative RDT rates due to non-expression of HRP2 are common (> 5%) (*12, 13*). The extent of misdiagnosis will depend on whether the parasites are dually (*pfhrp2* and *pfhrp3*) deleted or singly (*pfhrp2*) deleted and the brand of RDT used, because of the variability of HRP3 cross-reactivity with HRP2-specific test lines.

Ten *P. falciparum* RDT products were evaluated in round 8 that detect *P. falciparum* with Pf-LDH, two combination tests had only Pf-LDH, and seven had HRP2 as well. Of the seven with both HRP2 and Pf-LDH, four combined the two antigens on a single test line, and the other three had two separate test lines to detect *P. falciparum* (Table 1). All three products with separate Pf-LDH test lines met WHO performance criteria, with a *P. falciparum* PDS of 75% at 200 parasites/µL; however, in all three cases, this was due to the high PDS on the HRP2 line. The Pf-LDH test lines in all three products performed well at 2000 parasites/µL (PDS, 95–100%). As detection of Pf-LDH is known to be less sensitive than detection of HRP2 at low parasite density, low-density infections with HRP2-deleted *P. falciparum* parasites could be missed.

Tests that detect only HRP2 (without pLDH or aldolase lines) will be of limited use where non-*P.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 15.3, however, combination tests with both HRP2 and pan test lines should not be used to discriminate 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.

15.9.2 Species-specific vs non-species-specific RDTs

RDTs are tools mainly for making clinical decisions, but their role in surveillance has increased dramatically. If all infections are managed in the same way, i.e. with artemisinin-based combination therapy, there is no clinical advantage of using an RDT that can distinguish *P.falciparum* from non-*P.falciparum* infection: a pan-only test will suffice. If treatment of the two infections is different, however, distinguishing between *P.falciparum* and non-*P.falciparum* infection is a priority, and a combination test (Pf/Pan) must be used. When the results of RDTs are used for species-specific monitoring, a species-specific RDT (Pf/Pv) is preferable. No currently available RDT can specifically identify *P. malariae* or *P. ovale* infections. Furthermore, pan-species and Pvom tests are not evaluated against these infections, 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* (*47*).

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 and can be used in conjunction with the WHO list of prequalified IVDs.[1] 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, transport and storage conditions and price and supply aspects. 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 became a requirement for HRP2-*P. falciparum*-only RDTs on 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. 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 (21), Good practices for selecting and procuring rapid diagnostic tests for malaria (22)* and *Universal access to malaria diagnostic testing (23).*

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 diagnosis of malaria to regions and populations where good-quality microscopy-based analysis is impractical to maintain. This will allow implementation of WHO recommendation for 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-malaria causes of fever, including early pneumonia and sepsis (49). In order for an RDT programme to have its full potential impact on public health, it must therefore address not only malaria but also the management of other common and severe febrile illnesses that occur locally in the differential diagnosis of malaria.

16.1 WHO prequalification

The WHO programme for prequalification of IVD promotes access to good-quality tests by applying the principles of a comprehensive regulatory assessment. These include inspection of the manufacturer's quality management system, assessment of technical documentation (dossier review) and an independent performance evaluation.

Twelve malaria RDT products have been prequalified. Prequalification has not been required for eligibility for United Nations procurement tenders for malaria RDTs, as it is for other RDTs, such as for HIV; however, WHO prequalification has determined the eligibility of HRP2-*(4. falciparum*-only malaria RDTs for procurement since 1 January 2018. This requirement is expected to be extended to other RDT test types by the end of 2018. From round 8 onwards, all manufacturers interested in being eligible for WHO procurement must enter via the WHO prequalification process. Discrete rounds of testing will no longer be organized; rather, individual products or small batches of products will be tested continuously. For information on the prequalification process, see http://www.who.int/diagnostics_laboratory/evaluations/en/ (accessed 23 August, 2018), or contact diagnostics@who.int.

16.2 Provision of high-quality RDT services: 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 must, however, influence procurement decisions. An example of an algorithm, including an ease-of-use assessment, is provided in Annexes S2 and S3 to guide decisions.

[1] http://www.who.int/diagnostics_laboratory/evaluations/180806_prequalified_product_list.pdf?ua=1 (accessed 23 August 2018)

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 (*21*).

16.3 Post-market surveillance: lot verification

Post-market surveillance confirms the compliance of manufacturers with the expectations for quality 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 the tests available to the user. Post-market surveillance can be performed proactively through lot verification (described below), 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 a laboratory that performs 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. 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 during their shelf life and any anomalies observed during testing that might 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). Initial results are available after five days and definitive results after subsequent confirmatory tesing, if required. Details of the protocol can be found in the methods manual for lot testing (*34*). 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 programme, contact *Malaria_rdt@who.int* at least two 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 (*3–9*). The product testing programme has been 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 in the structure and expression of histidine-rich proteins. Furthermore, round 8 introduced a new component of the product evaluation: testing against a panel of HRP2-deleted *P. falciparum* samples. Publication of the results of past WHO product testing rounds has critically supported the WHO prequalification process, affected the procurement practices of countries and procurement agencies and contributed to a shift in the malaria RDT market towards better-performing products (*1*). This report of round 8 adds to the number of well-performing RDTs for which comprehensive performance data are now available and provides updated data on 14 product resubmissions.

18. References

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Annexes

Annex S1. Characteristics of evaluation panels used in rounds 1–8 of WHO malaria RDT product testing, 2008–2018

Currently, the basis for diagnosing malaria with antigen-detecting RDTs is detection in a patient's blood of one or more target malaria antigens, including HRP2 (*P. falciparum* only), pLDH (*Plasmodium* spp. pan-LDH), *P. falciparum* (Pf-LDH), non-*falciparum* (Pv-LDH, Pvom-LDH) 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 closely comparable (statistically equivalent). Antigen concentrations were thus quantified in triplicate in all panel samples by quantitative ELISA. Only results that were consistent in the triplicate runs and, when relevant, had a value factor close to 10 between the 200 and the 2000 parasites/µL dilutions 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 wide variation in antigen concentrations for the same parasite density. The possible explanations include differences in the level of antigen expression by isolates, in the duration of infection (accumulating antigens) and in the parasite growth stage at the time of collection (expressing different levels of antigen); the presence of circulating HRP2 from previous growth cycles; or HRP2 produced by parasites sequestered in the host's vascular tissues that cannot be accounted for in estimates of parasite density on blood slides.

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 that there was no statistically significant difference. Figs AS1.1–AS1.5 and tables AS1.1–AS1.5 show the distribution of antigen concentrations in all eight 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.

A new HRP2-negative *P. falciparum* panel was introduced in round 8. Therefore, the antigen concentrations in this panel could not be compared with those in previous rounds of HRP2-negative samples, but HRP2, pLDH and aldolase concentrations were compared with those in the phase-2 panel. The concentrations of pLDH and aldolase were comparable, while that of HRP2 was significantly lower. Fig. AS1.6 and Table AS1.6 show the distribution of antigen concentrations in the HRP2-negative and the phase 2 panel. The concentration of HRP2 was negligible in the HRP2-negative panel, with a median of 0.11 ng/mL, and was statistically significantly lower than the concentrations in the phase 2 panel. No statistically significant differences were seen between the phase 2 and the HRP2-negative panels for pLDH (Kruskal-Wallis test; $p > 0.5$). The mean and median aldolase concentrations in the HRP2-panel were higher than those in the phase-2 panel.

In the following box-and-whisker plots, the ends of the whiskers represent minimum and maximum values; the box represents the middle 50% of data, and the line through each box represents the median value; 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.

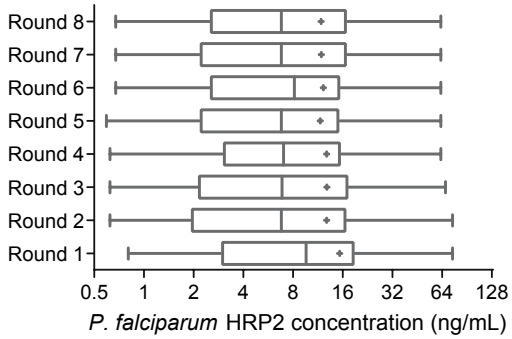


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

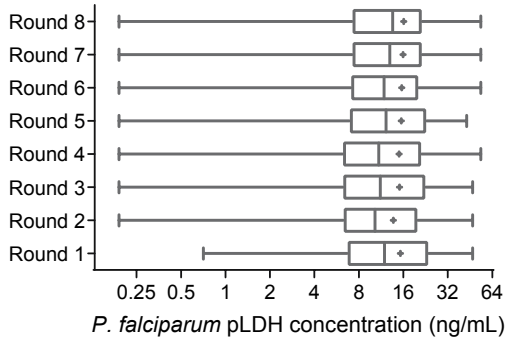


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

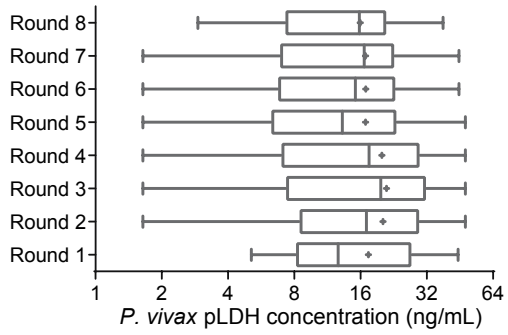


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

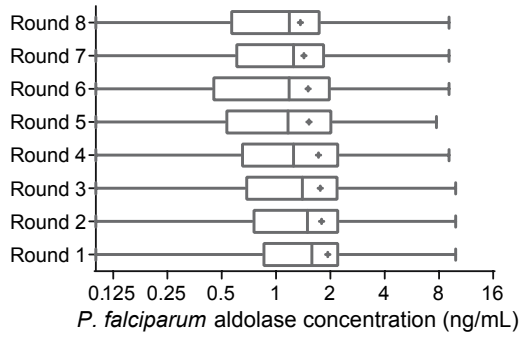


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

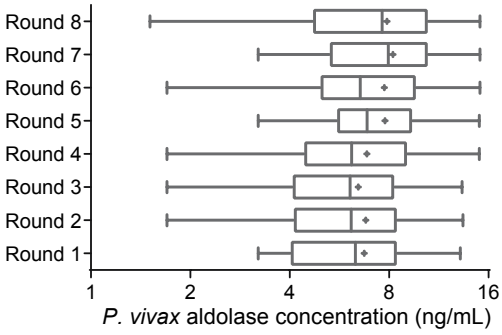


Figure AS1.6: Box-and-whisker plot of distribution of HRP2 (a), pLDH (b) and aldolase (c)concentration (ng/mL) in round 8 *P. falciparum* HRP2-negative panel and round 8 phase-2 panel

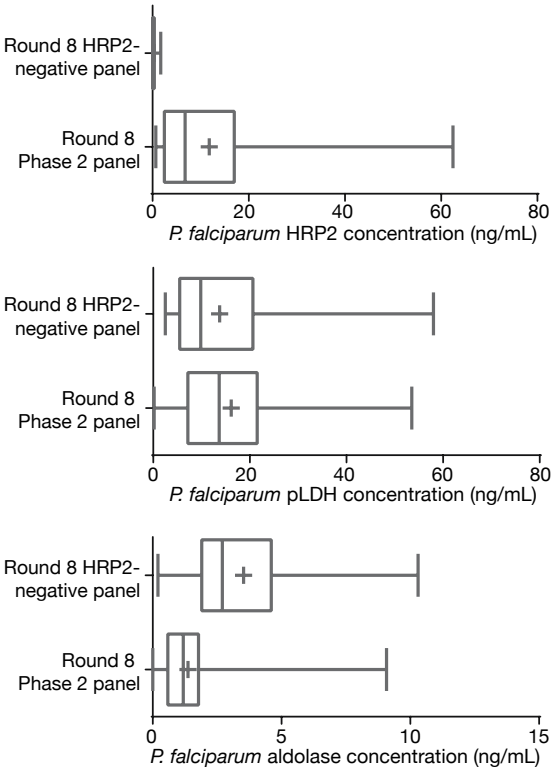


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7	Round 8
Number of values[a]	78	99	99	98	99	99	99	99
Minimum	0.80	0.62	0.62	0.62	0.59	0.67	0.67	0.67
25% percentile	2.90	1.90	2.10	2.97	2.15	2.48	2.15	2.48
Median	9.57	6.76	6.83	6.98	6.76	8.12	6.76	6.76
75% percentile	18.94	16.91	17.37	15.65	15.31	15.51	16.99	16.99
Maximum	73.70	73.70	66.70	62.48	62.48	62.48	62.48	62.48
Mean	15.28	12.70	12.77	12.72	11.65	12.15	11.83	11.82
Std. Deviation	16.98	15.75	15.19	14.72	13.25	13.29	13.01	13.02

[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	Round 8
Number of values[a]	74	93	92	92	94	98	98	98
Minimum	0.71	0.19	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	7.20
Median	11.95	10.31	11.18	10.92	12.24	11.85	12.99	13.68
75% percentile	23.75	20.10	22.70	21.28	23.05	20.36	21.51	21.51
Maximum	47.15	47.15	47.15	53.53	43.02	53.53	53.53	53.53
Mean	15.31	13.71	15.08	14.97	15.53	15.61	15.93	16.17
Std. Deviation	11.47	10.90	11.72	11.98	11.43	12.00	11.60	11.48

[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	Round 8
Number of values[a]	20	37	33	32	34	34	35	35
Minimum	5.10	1.64	1.64	1.64	1.64	1.64	1.64	3.03
25% percentile	8.10	8.40	7.30	6.96	6.26	6.72	6.86	7.26
Median	12.65	17.00	19.78	17.50	13.22	15.17	16.62	15.79
75% percentile	27.40	29.69	31.89	29.84	23.42	23.14	22.89	21.04
Maximum	44.40	47.90	47.90	47.90	47.90	44.79	44.79	37.94
Mean	17.38	20.24	20.99	20.00	16.84	16.90	16.87	16.04
Std. Deviation	11.57	13.27	13.55	13.00	12.59	11.78	11.17	9.86

[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	Round 8
Number of values[a]	77	98	99	97	98	99	99	99
Minimum	0.00	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	0.59
Median	1.58	1.49	1.40	1.25	1.17	1.18	1.25	1.19
75% percentile	2.25	2.25	2.23	2.25	2.07	2.02	1.88	1.78
Maximum	9.90	9.90	9.90	9.08	7.74	9.08	9.08	9.08
Mean	1.93	1.79	1.76	1.72	1.52	1.50	1.43	1.37
Std. Deviation	1.73	1.66	1.69	1.68	1.52	1.61	1.34	1.32

[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	Round 8
Number of values[a]	20	40	34	33	35	35	35	35
Minimum	3.21	1.70	1.70	1.70	3.21	1.70	3.21	2.74
25% percentile	4.02	4.11	4.07	4.41	5.55	4.94	5.27	4.69
Median	6.33	6.15	6.10	6.16	6.86	6.54	7.96	7.62
75% percentile	8.47	8.47	8.32	9.10	9.43	9.68	10.52	10.52
Maximum	13.15	13.40	13.30	15.00	15.00	15.08	15.08	15.08
Mean	6.73	6.81	6.45	6.86	7.78	7.74	8.22	7.96
Std. Deviation	2.89	3.15	2.90	3.23	3.30	3.69	3.61	3.80

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

Table AS1.6 Statistics for *P. falciparum* HRP2, pLDH and aldolase concentration (ng/mL) in the HRP2-negative panel and phase 2 (wild-type) panel

Antigen	HRP2		pLDH		aldolase	
Panel type	HRP2 neg.	Phase 2	HRP2 neg.	Phase 2	HRP2 neg.	Phase 2
Number of values	40	99	40	98	39	100
Minimum	0.00	0.67	2.50	0.19	0.20	0.00
25% percentile	0.00	2.48	5.48	7.20	1.90	0.55
Median	0.11	6.76	9.85	13.59	2.70	1.19
75% percentile	0.38	16.99	20.65	21.51	4.60	1.78
Maximum	1.70	62.48	58.00	53.53	10.30	9.08
Mean	0.27	11.76	13.75	16.13	3.53	1.36
Std. Deviation	0.29	12.96	11.59	11.49	2.36	1.32

Annex S2. Malaria RDT field assessment and anomalies

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

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

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

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

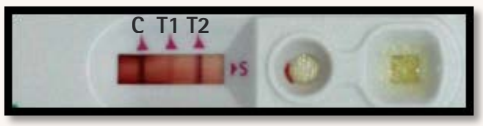
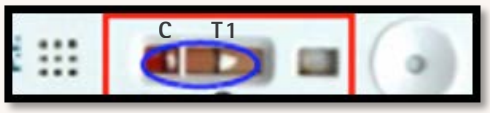
Date of assessment				
Commercial name				
Product code				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed package				
The correctly indicated number of RDTs are in the box				
Desiccant is included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

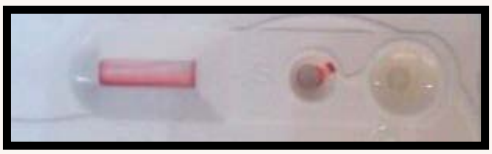
NA, not applicable

Fig. AS2.1 shows examples of observations and anomalies encountered and routinely recorded for RDTs in round 8 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 make it difficult for health workers to interpret the results. Furthermore, they should be reported to the manufacturers.

To complement field assessments, FIND and other collaborators, including WHO, published a "troubleshooting" guide for supervisors of malaria RDTs to provide practical recommendations for solving problems that may arise in the use of malaria RDTs and giving simple instructions on the actions to be taken if problems persist *(1)*. The list of problems discussed was based on extensive experience from various field studies and from the RDT product and lot testing programmes.

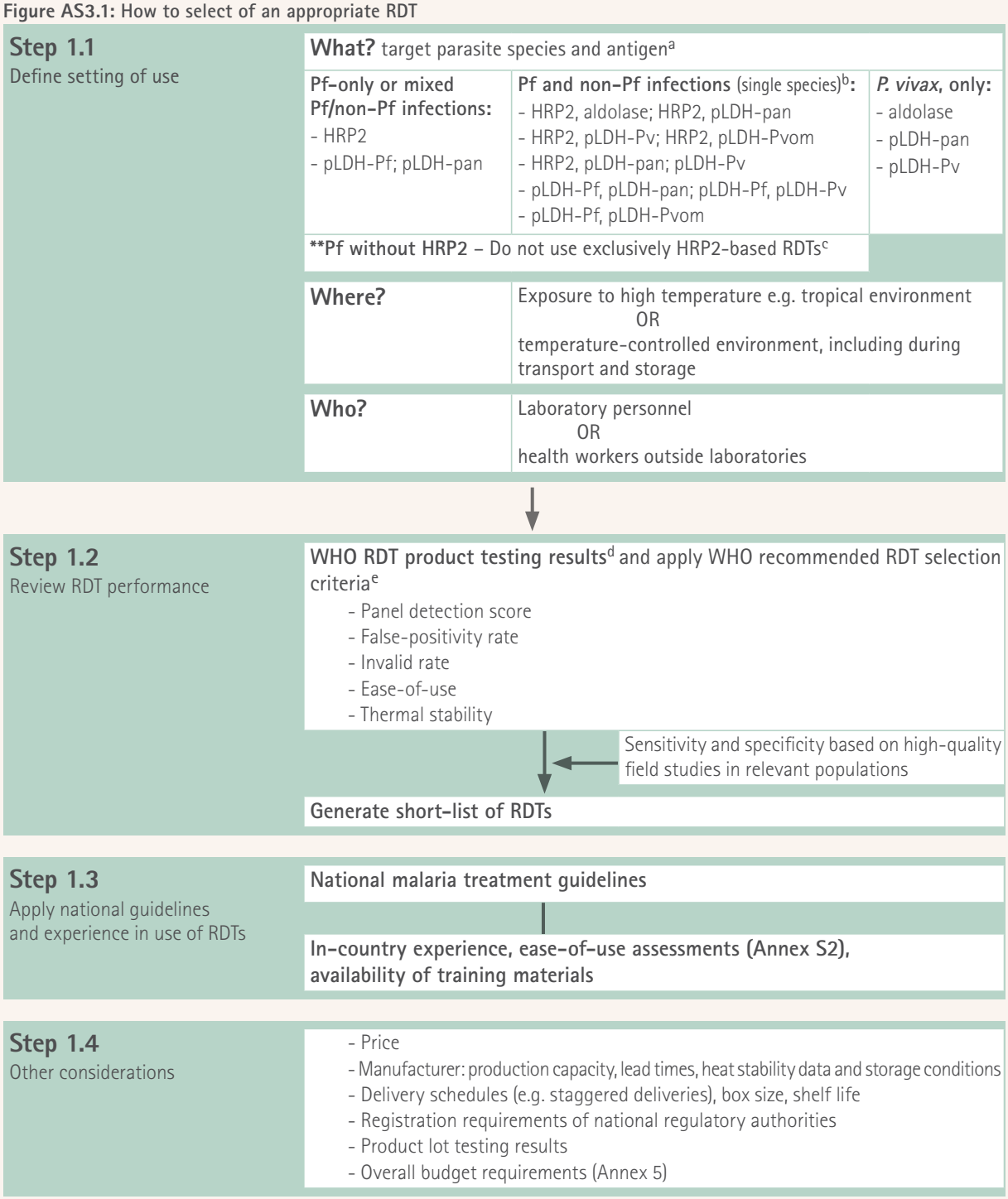
Figure AS2.1: Malaria RDT anomalies encountered in production lots

a) Observations on the test strip		
Red background		Background staining is relatively common. In this example, the result is positive as test lines are positive; however, a more intense red background may obscure weak positive test lines, giving false-negative results.
Incomplete clearing		In this example, the result is positive as the test line is visible. Poor clearing of blood may obscure weak positive test lines, giving false-negative results.
b) Observations of flow problems		
Failed migration		Blood and buffer did not run the length of the strip
Incomplete migration		One portion of the nitrocellulose near the test band was not absorptive and remained dry during wicking, creating irregular migration of blood/buffer with red background. In this example, the result is positive, as the test line is clearly visible.
c) Observations on test lines		
Ghost test lines		White lines on a stained background. In this example, the result is negative, as the test line is not dark and is thus not visible.
Patchy broken test line(s)		The test line is visible but interrupted (broken).
Diffuse test line(s)		Test line wider than control, without clearly defined edge.

d) RDT structural problems		
Strip misplaced in the cassette (shift)		Strip can be seen only partially in the results window.
Specimen pad not seen in sample window		Normally, the colour of the conjugated antibody can be seen in the sample window (commonly purple, pink or blue).
Buffer remains pooled in the buffer well		The buffer is not completely absorbed and this may result in failed migration or incomplete clearing.

Annex S3. Selection of an appropriate RDT

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



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

[b] Tests with a *P. falciparum*-specific line and a 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-LDH) 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 *pfhrp2+/- pfhrp3* genes have been identified with high frequency in parts of South America, Africa (Democratic Republic of the Congo, Eritrea, Ghana) and India (*2–7*).

[d] See references *(8–14)*.

[e] WHO RDT procurement criteria *(15)*: http://www.who.int/malaria/publications/atoz/rdt_selection_criteria/en/ (accessed 28 August 2018).

For a comprehensive guide to procurement of malaria RDTs, from selection to quantification, budgeting, technical specifications, management of tenders, contracts, supply management and monitoring of supplier performance and managing product variations, see *Recommended selection criteria for procurement of malaria rapid diagnostic tests (15)*.

Annex 1: Characteristics of RDTs evaluated in round 8

Manufacturer	Product Name	Product codes	Lot Numbers	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[d]	Results Interpretation[e] (type A–J)	Format type[f]	Recommended storage temperature (°Celcius)
				Control	Test line 1[a] (T1)	Test line 2[a] (T2)	Test line 3 (T3)								
Access Bio Ethiopia	CareStart™Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	MR16M73, MR16M74		pan-LDH	HRP2		5	2	20		1	C	Cassette	1-40°
	CareStart™Malaria PAN (pLDH) Ag RDT	RMNM-02591	MN16M55, MN16M56		pan-LDH			5	2	20		1	B	Cassette	1-40°
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	MP16M63, MP16M64		Pf-LDH/ HRP2			5	2	20		1	A	Cassette	1-40°
Access Bio, Inc.	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	MO17A61, MO17A62		HRP2			5	2	20		1	A	Cassette	1-40°
	CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	MR17A61, MR17A62		pan-LDH	HRP2		5	2	20		1	C	Cassette	1-40°
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	MP17A61, MP17A62		Pf- LDH/ HRP2			5	2	20		1	A	Cassette	1-40°
	CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	MW17A61, MW17A62		Pvom-LDH	HRP2		5	2	20		1	H	Cassette	4-30°
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	ML17A61, ML17A62		pan-LDH	Pf-LDH		5	2	20		1	C	Cassette	4-30°
	CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	MS17A61, MS17A62		Pf-LDH	HRP2		5	2	20		1	J	Cassette	1-40°
	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	MV17A61, MV17A62		Pv-LDH	HRP2		5	2	20		1	E	Cassette	1-40°
Advy Chemical Pvt. Ltd.	EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	MAFP01/0117, MAFP02/0117		Pf-LDH			5	4	20	30	3	A	Cassette	2-40°
	EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II)	RK MAL 025-25	MAFPH01/0117, MAFPH02/0117		Pf-LDH	HRP2		5	4	20	30	3	C	Cassette	2-40°
ASPEN LABORATORIES PVT.LTD	Aspen® Mal (Ag Pf/Pv) Rapid Card Test	A61660E	28017/1, 28017/2		Pv-LDH	HRP2		5	3	20	30	2	E	Cassette	2-40°
Assure Tech (Hangzhou)	Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	5R1611164, 5R1701025		pan-LDH	HRP2		10	3 + 1 (5min)	15	20	13	C	Cassette	2-30°
Hangzhou AllTest Biotech Co. Ltd.	Malaria P.f./ Pan Rapid Test Cassettee	IMPN-402	MAL17010010, MAL17010011		pan-aldolase	HRP2		5	3	10	20	10	C	Cassette	2-30°
Karwa Enterprises pvt ltd	Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	30017/1, 30017/2		Pv-LDH	HRP2		5	3	20	30	2	E	Cassette	2-40°
Meril Diagnostics Pvt Ltd.	MERISCREEN Malaria pLDH Ag	MVLRPD-02	MI011728R, MI011729R		pan-LDH	Pf-LDH		5	4	20	30	3	C	Cassette	1-40°
	MERISCREEN Malaria Pf / Pan Ag	MHLRPD-02	MI011726R, MI011727R		pan-LDH	HRP2		5	4	20	30	3	C	Cassette	1-40°
Nantong Egens Biotechnology Co., Ltd.	EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	20170120, 20170123		Pv-LDH	HRP2		5	2	20		1	E	Cassette	2-30°
Nectar Lifesciences Limited	Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	MAGDR00117, MAGDR00217		Pv-LDH	HRP2		5	2	20		1	E	Cassette	4-30°
Omega Diagnostics Ltd.	VISITECT® Malaria Pf/Pan	0D326	100022, 100025		pan-LDH	HRP2		5	3	20	30	2	C	Cassette	4-30°
	VISITECT® Malaria Pf/Pv	0D216	100021, 100024		Pv-LDH	HRP2		5	3	20	30	2	E	Cassette	4-30°
	VISITECT® Malaria Pf	OD336	100020, 100023		HRP2			5	3	20	30	2	A	Cassette	4-30°
Orchid Biomedical Systems (Tulip Group)	Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	311769, 311770		HRP2			5	2	20		1	A	Cassette	4-45°
Premier Medical Corporation Private Ltd.	First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	76A01175, 76A02175		Pv-LDH	HRP2		5	2	20	30	1	E		1-40°

(continued)

Annex 1: Characteristics of RDTs evaluated in round 8 *(continued)*

Manufacturer	Product Name	Product codes	Lot Numbers	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[d]	Results Interpre-tation[e] (type A-J)	Format type[f]	Recom-mended storage temperature (°Celcius)
				Control	Test line 1[a] (T1)	Test line 2[a] (T2)	Test line 3 (T3)								
SD Biosensor	STANDARD Q Malaria P.f Ag Test	09MAL10B	QML1016006, QML1016007		HRP2			5	3	15	30	6	A	Cassette	2-40°
	STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	QML3016006, QML3016007		pan-LDH	HRP2		5	3	15	30	6	C	Cassette	2-40°
	STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	QML 2016006, QML2016007		Pv-LDH	HRP2		5	3	15	30	6	E	Cassette	2-40°
Standard Diagnostics Inc. (Alere)	SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	05GDB004A, 05GDB005A		Pv-LDH	Pf-LDH	HRP2	5	4	15	30	7	K	Cassette	1-40°
	SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	05FDB008A, 05FDB009A		Pf-LDH	HRP2		5	4	15	30	7	J	Cassette	1-40°
WELLS BIO, INC	careUSTM Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	RMR17A261, RMR17A262		pan-LDH	HRP2		5	2	20		1	C	Cassette	1-40°
	careUSTM Malaria PAN (pLDH) Ag	RMN-M02582	RMN17A241, RMN17A242		pan-LDH			5	2	20		1	B	Cassette	1-40°
	careUSTM Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	RMP17A231, RMP17A232		HRP2 / Pf-LDH			5	2	20		1	A	Cassette	1-40°
Zephyr Biomedicals	FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	81223, 81224		Pv-LDH	HRP2		5	2	20		1	E	Cassette	1-40°
	Parascreen® Rapid Test for Malaria Pan/Pf	503030025	101289, 101290		pan-LDH	HRP2		5	2	20		1	C	Cassette	4-30°

[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 (C), far left

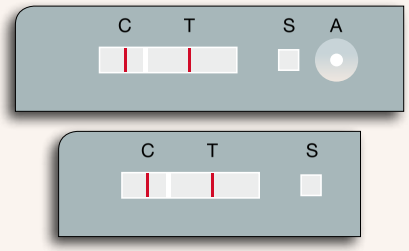
[c] From placement of buffer, or from 'intermediate' step, if applicable

[d] 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 ; group 13: 10µL, 3+1 drops, 15 mins.

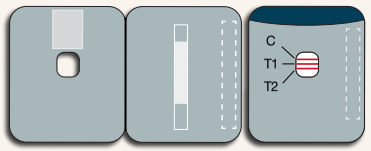
[e] See Annex 2

[f] 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.

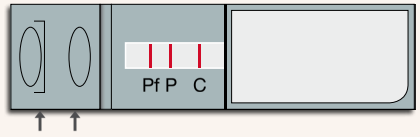
A Cassette



B Card

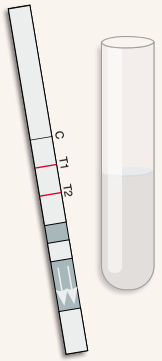


C Cassette hybrid



Sample and mixing wells

D Dipstick

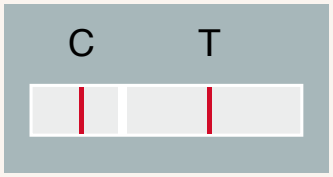


E Other

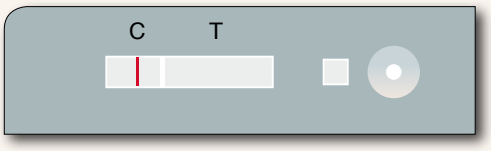
Annex 2: Malaria RDTs: guide to interpretation of results

Type A: Guide to results of generic Pf malaria RDTs

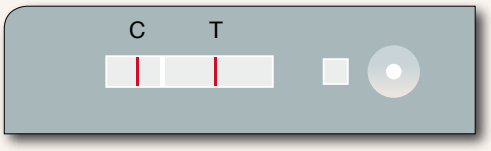
Results window: C=control line; T=test line with bound HRP2 or Pf-specific pLDH antibody.



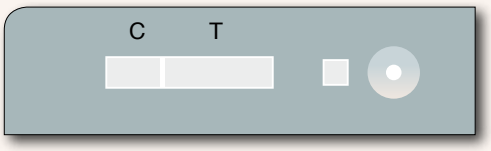
Negative results: One line 'C' appears in the results window.

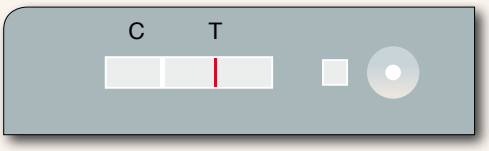


Positive results: *P. falciparum* infection. Two lines 'C' and 'T' appear in the results window. Test is positive even if the test line is faint.



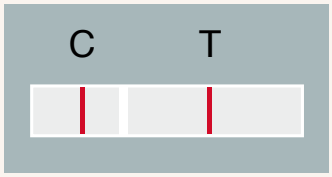
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



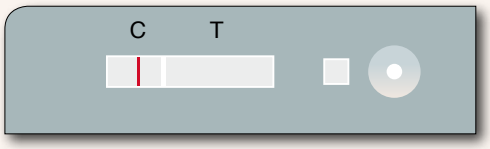


Type B: Guide to results of generic major *Plasmodium* species (pan) malaria RDTs

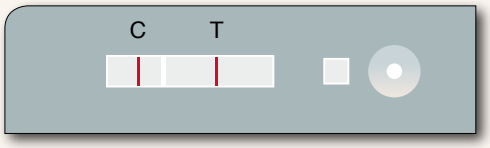
Results window: C=control line; T=test line with bound pan-specific pLDH or aldolase antibody.



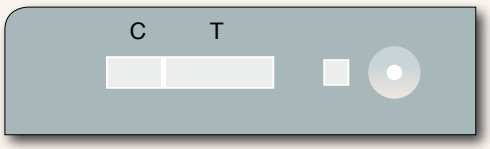
Negative results: One line 'C' appears in the results window.

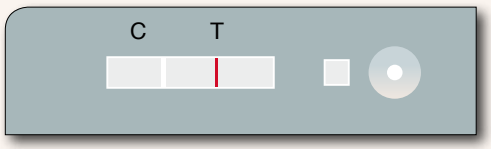


Positive results: *Plasmodium* species (*P. falciparum*, *P. vivax*, *P. malariae*, *P. ovale*) infection. Two lines 'C' and 'T' appear in the results window. Test is positive even is the test line is faint.



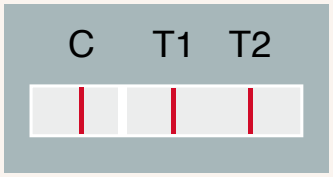
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



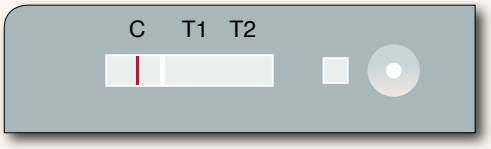


Type C: Guide to results of generic pan-Pf malaria RDTs

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.

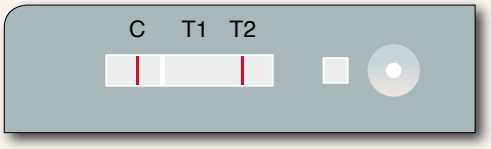


Negative results: Only one line 'C' appears in the results window.

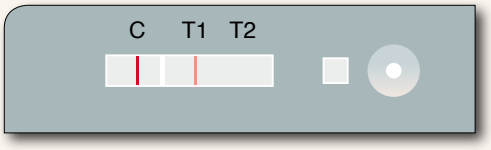


Positive results:

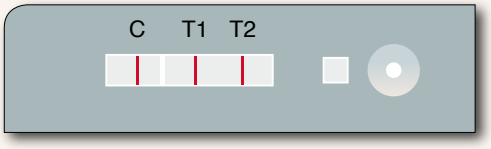
P. falciparum: Two lines 'C' and 'T2" appear in the results window.



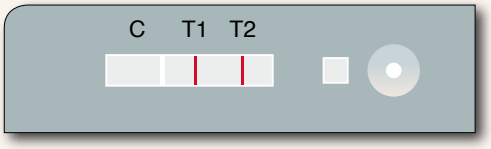
Non-*falciparum* infection (*P. vivax, P. ovale, P. malariae*) or mixed infection:
Two lines 'C' and 'T1" appear in the results window.

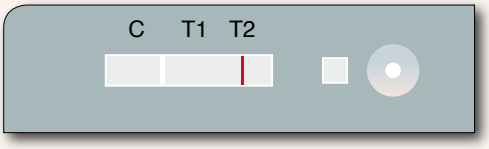


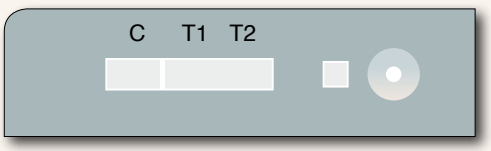
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

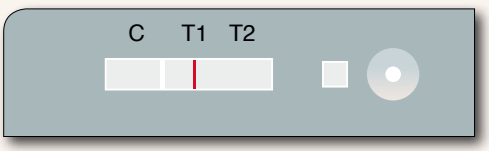


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



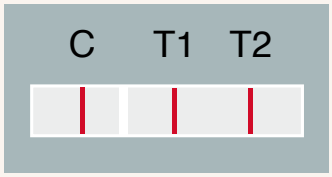




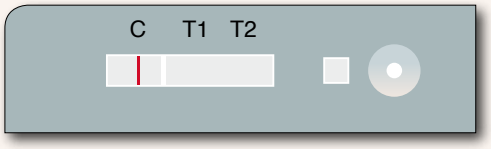


Type D: Guide to results of generic Pf-pan malaria RDTs

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.

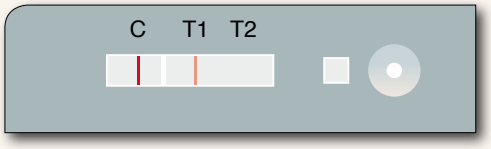


Negative results: Only one line 'C' appears in the results window.

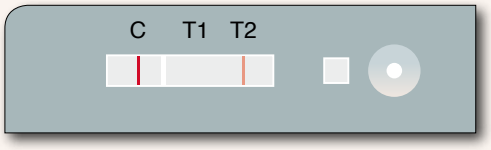


Positive results:

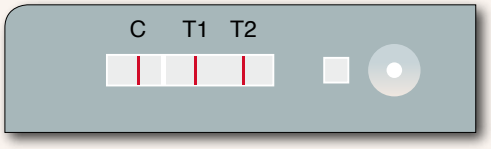
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



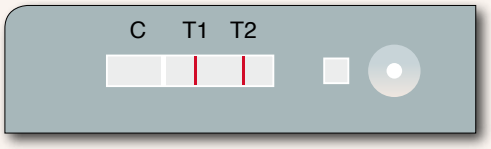
Non-*falciparum* infection (*P. vivax*, *P. ovale*, *P. malariae*) or mixed infection.
Two lines 'C' and 'T2' appear in the results window.

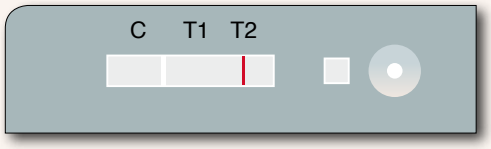


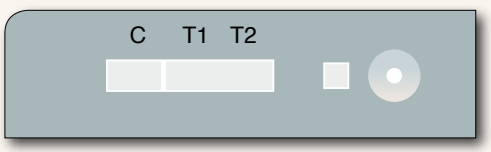
P. falciparum or mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

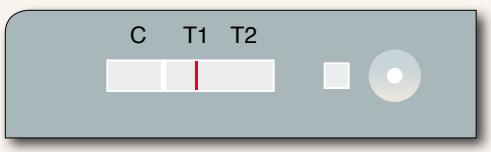


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



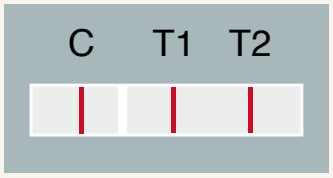




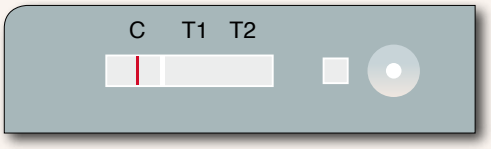


Type E: Guide to results of generic Pv-Pf malaria RDTs

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.

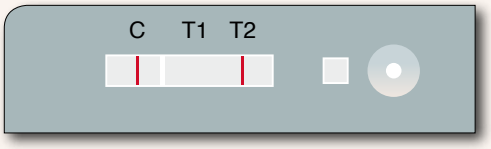


Negative results: Only one line 'C' appears in the results window.

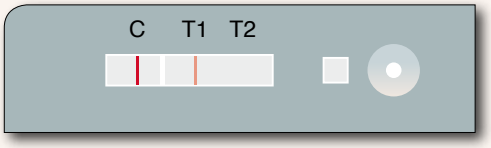


Positive results:

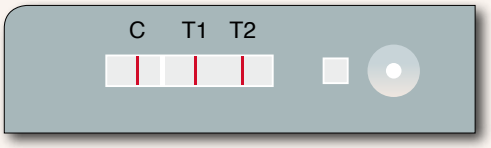
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



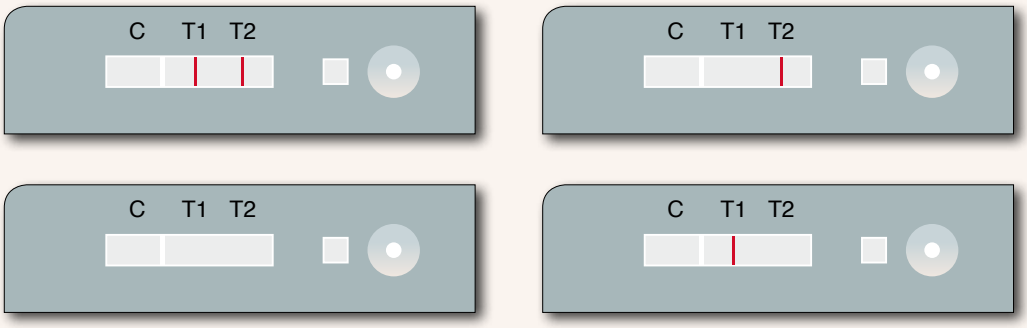
P. vivax infection. Two lines 'C' and 'T1' appear in the results window.



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

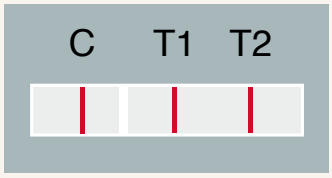


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

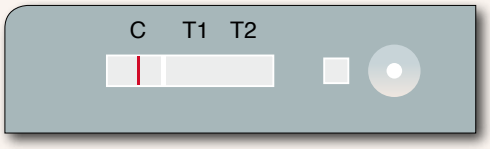


Type F: Guide to results of generic Pf-Pv malaria RDTs

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.

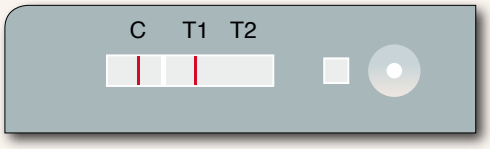


Negative results: Only one line 'C' appears in the results window.

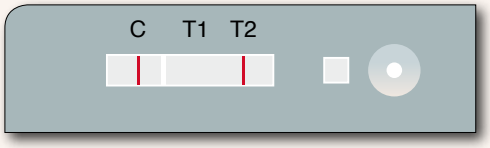


Positive results:

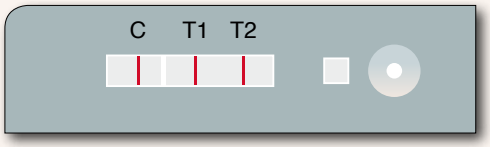
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



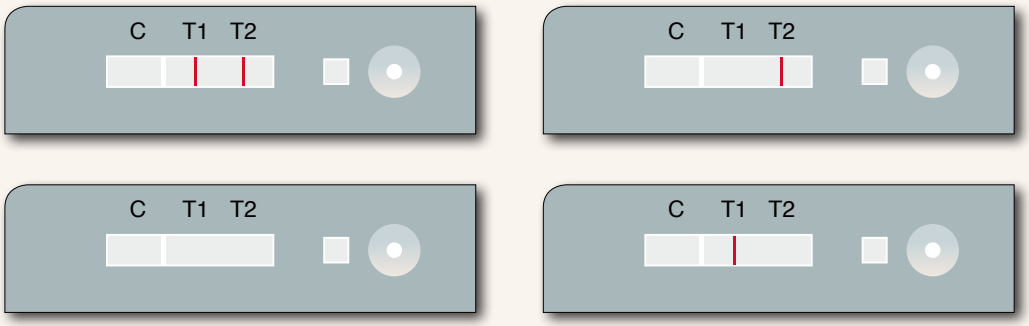
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



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

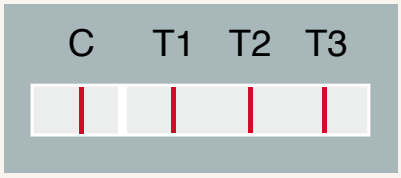


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

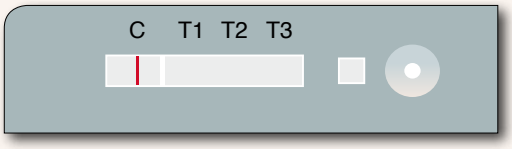


Type G: Guide to results of generic pan-Pv-Pf malaria RDTs

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

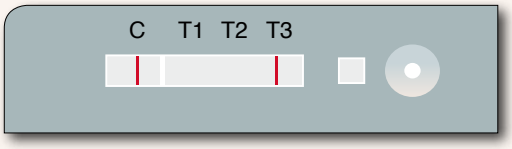


Negative results: Only one line 'C' appears in the results window.

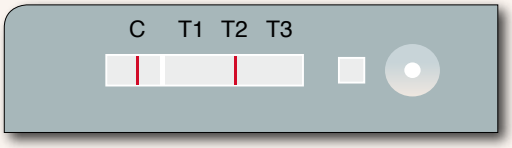


Positive results:

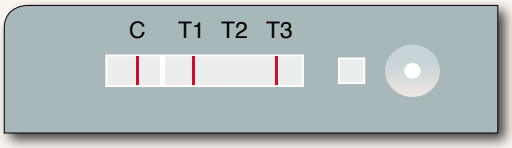
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



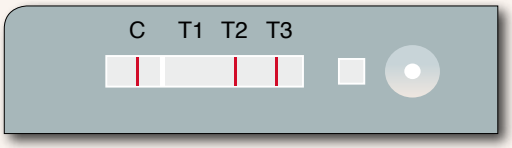
P. vivax infection. Two lines 'C' and 'T2' appear in the results window.



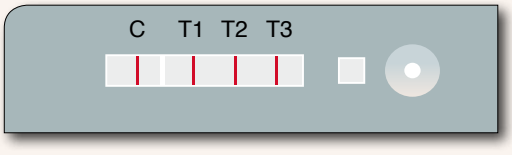
P. falciparum with or without mixed infection with *P. ovale* or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



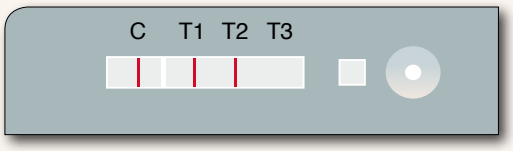
P. falciparum and *P. vivax* mixed infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



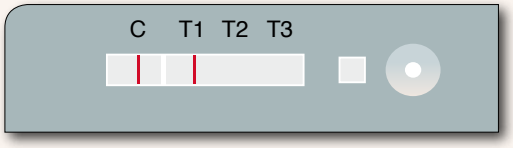
P. falciparum and *P. vivax* mixed infection with or without *P. ovale* and/or *P. malariae* infection.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



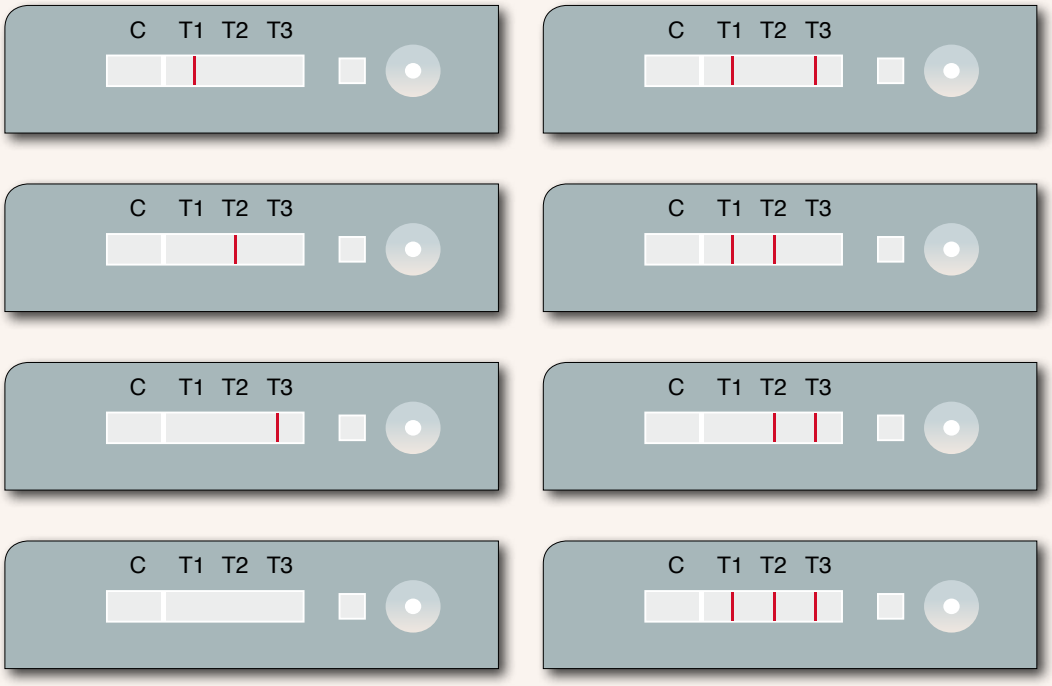
***P. vivax* with or without *P. ovale* and/or *P. malariae* infection. Three lines 'C', 'T1' and 'T2' appear in the results window.**



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

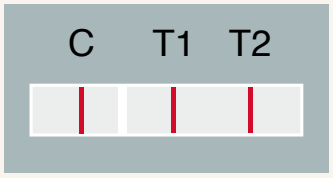


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

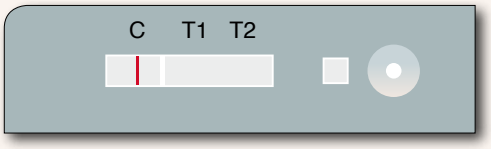


Type H: Guide to results of generic vom[1]-Pf malaria RDTs

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

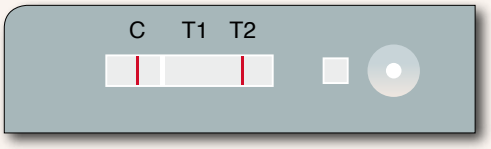


Negative results: Only one line 'C' appears in the results window.

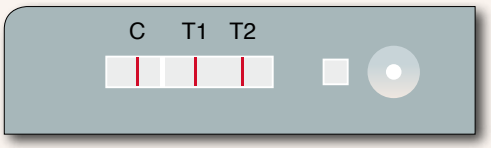


Positive results:

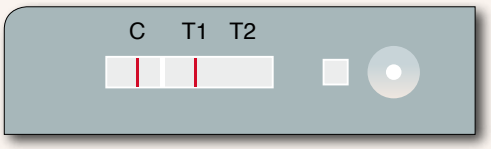
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



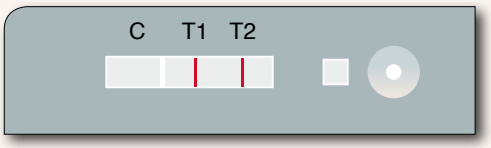
P. falciparum mixed infection (with *P. vivax*, *P. ovale* and/or *P. malariae*). Three lines 'C', 'T1' and 'T2' appear in the results window.

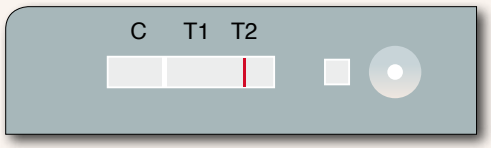


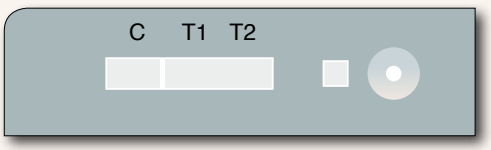
Non-*P. falciparum* infection (*P. vivax*, *P. ovale* and *P. malariae*) or mixed infection. Two lines 'C' and 'T1' appear in the results window.

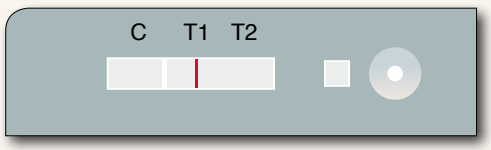


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.





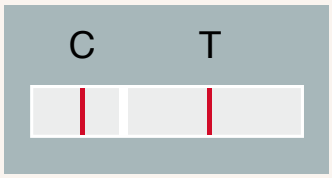




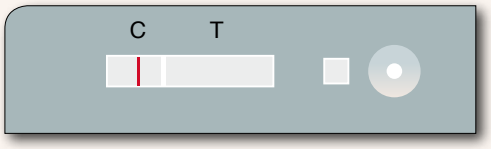
[1] vom, *P. vivax*, *P. ovale*, *P. malariae*

Type I: Guide to results of generic Pv malaria RDTs

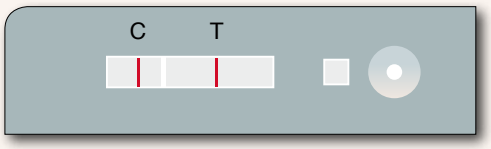
Results window: C=control line; T=test line with bound *P. vivax*-specific pLDH.



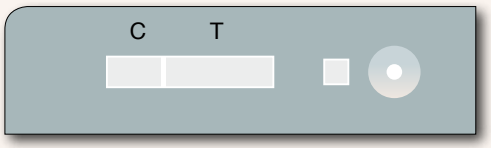
Negative results: Only one line 'C' appears in the results window.

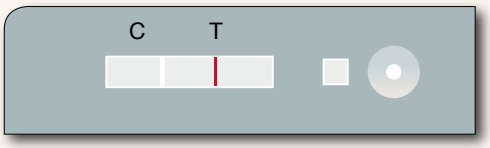


Positive results: *P. vivax* infection. Two lines 'C' and 'T' appear in the results window.



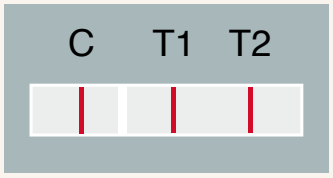
Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



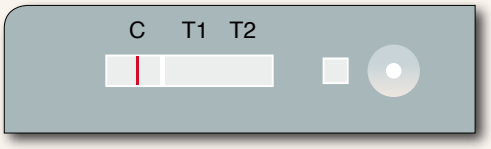


Type J: Guide to results of generic Pf-Pf malaria RDTs

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

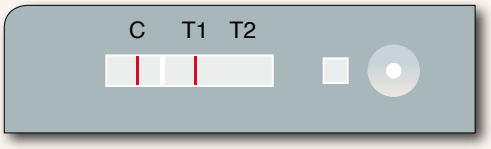


Negative results: Only one line 'C' appears in the results window.

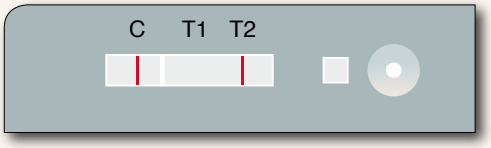


Positive results:

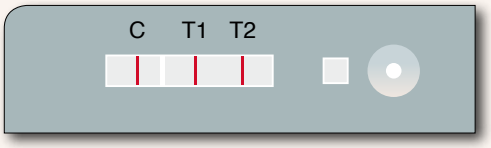
P. falciparum infection. Two lines 'C' and 'T1' appear in the results window.



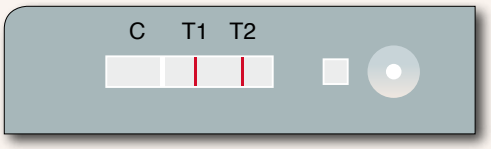
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.

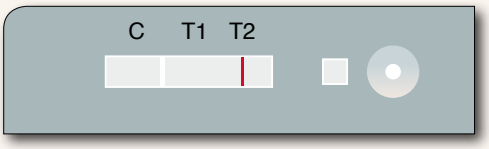


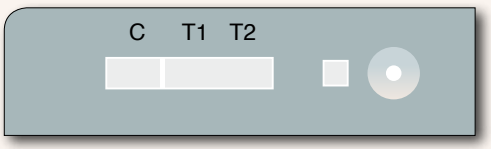
P. falciparum infection. Three lines 'C', 'T1' and 'T2' appear in the results window.

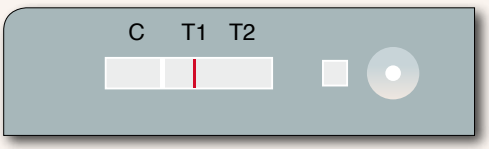


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.



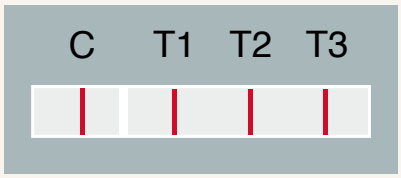




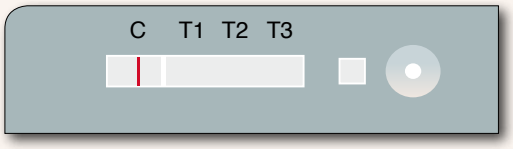


Type K: Guide to results of generic Pv-Pf-Pf malaria RDTs

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).

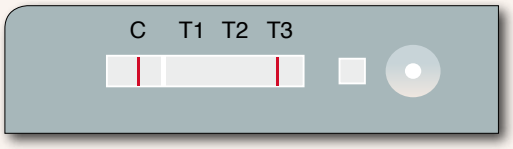


Negative results: Only one line 'C' appears in the results window.

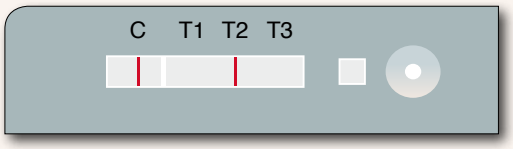


Positive results:

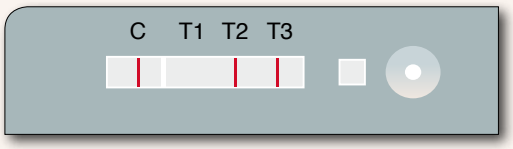
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



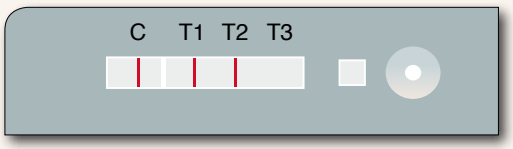
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



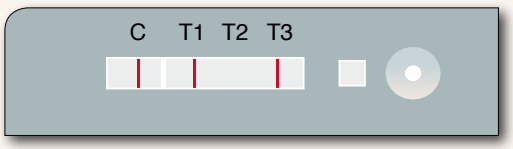
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



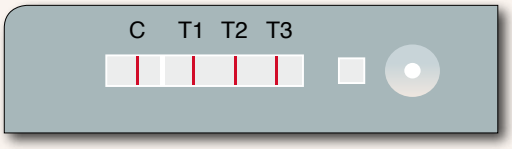
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T2' appear in the results window.



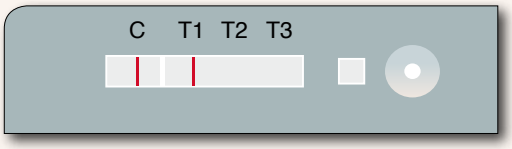
P. falciparum infection and *P. vivax* mixed infection. Three lines 'C', 'T1' and 'T3' appear in the results window.



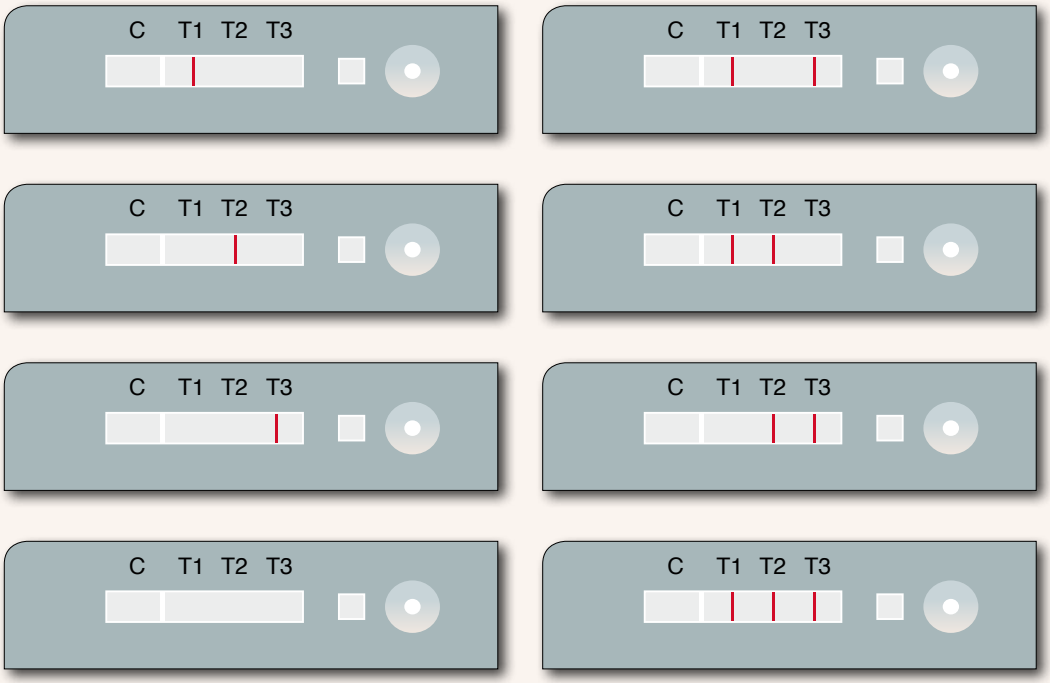
P. falciparum infection and *P. vivax* mixed infection. Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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

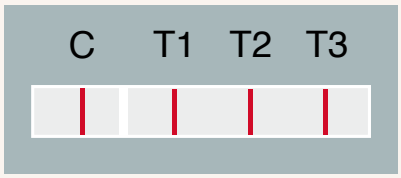


Invalid results: No 'C' line appears in the results window. Repeat the test with a new RDT if no control line appears.

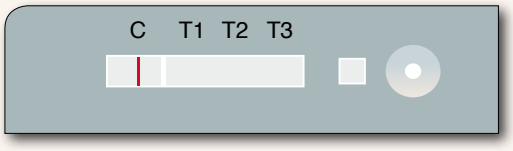


Type L: Guide to results of generic pan-Pf-Pf malaria RDTs

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)

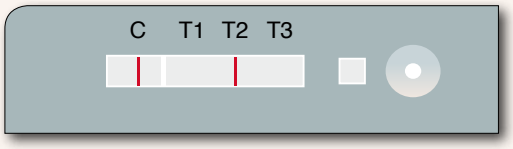


Negative results: Only one line 'C' appears in the results window.

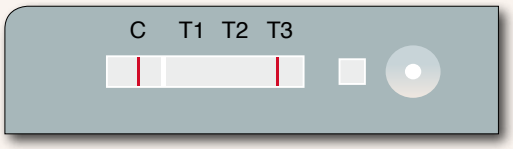


Positive results:

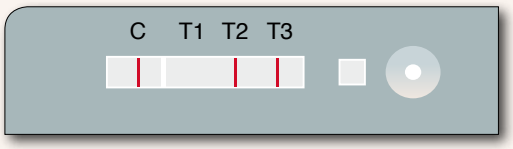
P. falciparum infection. Two lines 'C' and 'T2' appear in the results window.



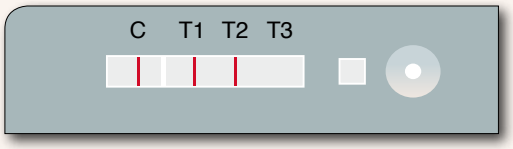
P. falciparum infection. Two lines 'C' and 'T3' appear in the results window.



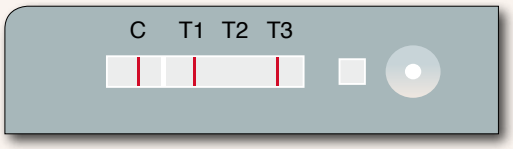
P. falciparum infection. Three lines 'C', 'T2' and 'T3' appear in the results window.



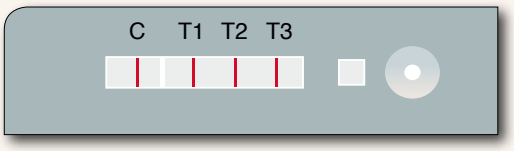
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T2' appear in the results window.



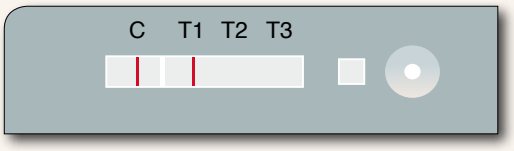
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*. Three lines 'C', 'T1' and 'T3' appear in the results window.



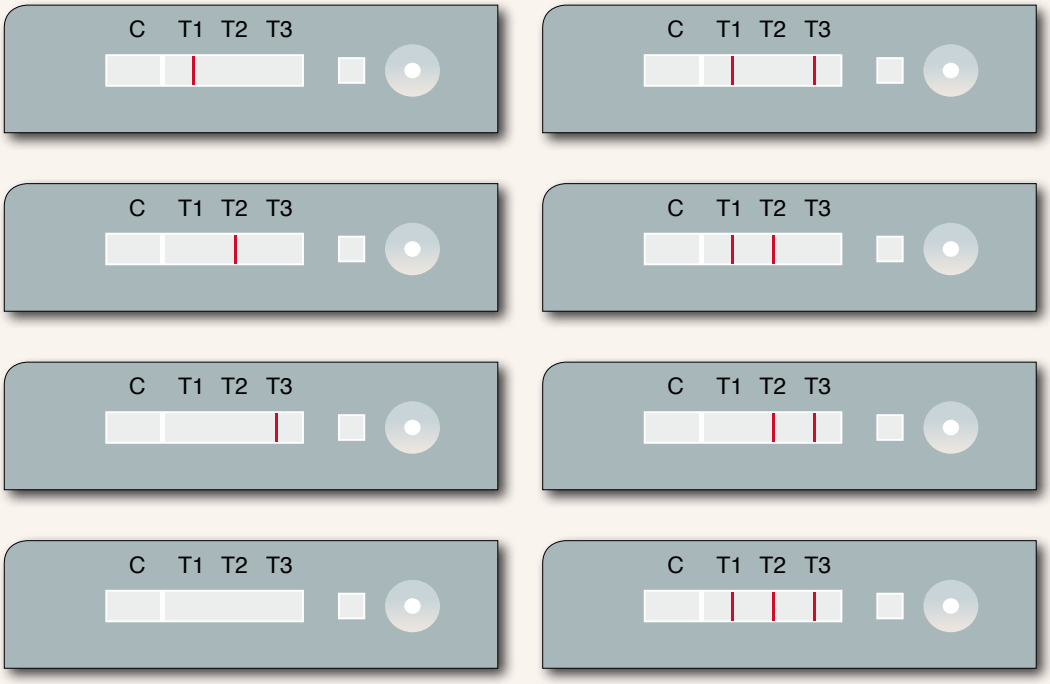
P. falciparum infection with or without mixed infection with *P. vivax*, *P. ovale* and/or *P. malariae*.
Four lines 'C', 'T1', 'T2' and 'T3' appear in the results window.



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 variation 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										
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT	RMSM-02571	Access Bio Inc.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	20	20	20	20	20	20	20	20
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	20	19	19	20	20	20	20	20
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II)	RK MAL 025-25	Advy Chemical Pvt. Ltd.	19	20	19	19	20	19 (19)	20	20
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	10	13	8	3	4	1 (15)	20	20
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	20	20	20	19	20	19 (19)	20	20
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)	05FK90	Standard Diagnostics Inc. (Alere)	20	20	20	20	20	20	20	20
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	20	20	20	20	19	19 (19)	20	20
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	20	19 (19)	19 (19)	20	20	20	20	20
Pf and pan										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	20	19	19	20	20	20	20	20
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	20	20	20	20	20	20	20	20
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	14	15	13	17	17	16 (18)	20	20
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	20	20	20	16	18	15 (16)	20	20
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	20	20	20	20	19	19 (19)	20	20
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	9	9	6	12	16	11 (14)	20	20
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	20	20	20	20	20	20	20	20
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	20	20	20	20	20	20	20	19 (19)
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	20	20	20	20	20	20	20	20
Pf and Pv/Pvom										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	20	20	20	20	20	20	20	20
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	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
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	20	20	20	20	20	20	20	20
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	20	20	20	20	20	20	20	20
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	20	20	20	20	20	20	20	20
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	20	20	20	20	20	20	19	20
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	20	19 (19)	19 (19)	20	20	20	18 (18)	20
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	20	20	20	19 (19)	20	19	20	20
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	20	20	20	20	20	20	20	20
Pan only										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	20	19	19	20	20	20	20	20
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	20	20	20	20	20	20	20	20
Pf, Pf and Pv										
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	20	20	20	20	20	20	20	20

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

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

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

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

Product	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																						
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	0.0	3.8	65.0	25.0	6.3	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - HRP2 band	RMSM-02571	Access Bio Inc.	0.0	11.3	67.5	15.0	6.3	0.0	0.0	0.0	7.5	92.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			58.8	41.3	0.0	0.0	0.0	5.0	12.5	80.0	2.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	0.0	3.8	71.3	23.8	1.3	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	0.0	6.3	66.3	25.0	2.5	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	1.3	8.8	72.5	16.3	1.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II) - HRP2 band	RK MAL 025-25	Advy Chemical Pvt. Ltd.	3.8	86.3	10.0	0.0	0.0	0.0	12.5	65.0	20.0	2.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II) - pLDH band			20.0	80.0	0.0	0.0	0.0	0.0	57.5	42.5	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	62.5	37.5	0.0	0.0	0.0	0.0	70.0	30.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	1.3	8.8	71.3	17.5	1.3	0.0	0.0	0.0	17.5	82.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	0.0	3.8	78.8	16.3	1.3	0.0	0.0	0.0	20.0	80.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band	05FK90	Standard Diagnostics Inc. (Alere)	21.3	77.5	1.3	0.0	0.0	0.0	2.5	95.0	2.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	1.3	3.8	76.3	17.5	1.3	0.0	0.0	0.0	27.5	72.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	0.0	5.0	67.5	23.8	3.8	0.0	0.0	0.0	12.5	87.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																						
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0.0	12.5	56.3	27.5	3.8	0.0	0.0	0.0	5.0	95.0	11.3	88.8	0.0	0.0	0.0	0.0	0.0	77.5	22.5	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	7.5	62.5	22.5	7.5	0.0	0.0	0.0	5.0	95.0	38.8	61.3	0.0	0.0	0.0	0.0	7.5	92.5	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	1.3	12.5	72.5	12.5	1.3	0.0	0.0	2.5	10.0	87.5	53.8	46.3	0.0	0.0	0.0	0.0	5.0	82.5	12.5	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0.0	5.0	75.0	17.5	2.5	0.0	0.0	0.0	2.5	97.5	12.5	87.5	0.0	0.0	0.0	0.0	2.5	90.0	7.5	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	21.3	62.5	16.3	0.0	0.0	0.0	2.5	35.0	40.0	22.5	96.3	3.8	0.0	0.0	0.0	5.0	85.0	10.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	7.5	80.0	12.5	0.0	0.0	0.0	0.0	52.5	40.0	7.5	92.5	7.5	0.0	0.0	0.0	25.0	72.5	2.5	0.0	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	1.3	25.0	56.3	13.8	3.8	0.0	0.0	0.0	37.5	62.5	13.8	86.3	0.0	0.0	0.0	0.0	7.5	80.0	12.5	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	42.5	57.5	0.0	0.0	0.0	0.0	30.0	70.0	0.0	0.0	53.8	46.3	0.0	0.0	0.0	2.5	17.5	80.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	45.0	40.0	15.0	0.0	0.0	0.0	5.0	95.0	85.0	15.0	0.0	0.0	0.0	0.0	32.5	65.0	2.5	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	3.8	78.8	15.0	2.5	2.5	0.0	0.0	27.5	70.0	48.8	51.3	0.0	0.0	0.0	2.5	50.0	47.5	0.0	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	0.0	10.0	70.0	20.0	0.0	0.0	0.0	0.0	15.0	85.0	46.3	53.8	0.0	0.0	0.0	0.0	35.0	65.0	0.0	0.0
Pf and Pv/Pvom																						
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	0.0	21.3	68.8	10.0	0.0	0.0	0.0	2.5	35.0	62.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	0.0	27.5	61.3	11.3	0.0	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

Table A3.2 *(continued)*

Product	Product code	Manufacturer	200 parasites/µL					2000 parasites/µL					200 parasites/µL					2000 parasites/µL				
			Percentage distribution of Pf test band intensity[b] (n=80)					Percentage distribution of Pf test band intensity[b] (n=40)					Percentage distribution of Pan test band intensity[b] (n=80)					Percentage distribution of Pan test band intensity[b] (n=40)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	20.0	67.5	11.3	1.3	0.0	0.0	0.0	10.0	90.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0.0	2.5	65.0	26.3	6.3	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	1.3	61.3	31.3	6.3	0.0	0.0	0.0	5.0	95.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0.0	6.3	68.8	23.8	1.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	16.3	66.3	16.3	1.3	2.5	0.0	2.5	20.0	75.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0	6.3	70.0	22.5	1.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	1.3	6.3	72.5	18.8	1.3	0.0	0.0	0.0	17.5	82.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0.0	15.0	73.8	11.3	0.0	0.0	0.0	5.0	10.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pan only																						
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.3	7.5	63.8	26.3	1.3	0.0	0.0	0.0	22.5	77.5
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	8.8	77.5	13.8	0.0	0.0	0.0	2.5	2.5	95.0
Pf, Pf and Pv																						
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	0.0	3.8	78.8	16.3	1.3	0.0	0.0	0.0	15.0	85.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f/P.f/P.v - Pf-LDH band	05FK120	Standard Diagnostics Inc. (Alere)	28.8	71.3	0.0	0.0	0.0	0.0	0.0	95.0	5.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

NA, not applicable

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

[a] Denotes no band visible

[b] Calculations include invalid tests

Annex 4: Phase-2 results

Table A4.1: Lot variation in positive results against phase-2 wild-type *P. falciparum* and *P. vivax* samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	Manufacturer	*P. falciparum* samples (n=100) Total positive results[a] returned								*P. vivax* samples (n=35) Total positive results[a] returned							
			200 parasites/µL						2000[b] parasites/µL		200 parasites/µL						2000 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																		
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	96	94	92	95	96 (99)	94 (99)	100	100	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT[d]	RMSM-02571	Access Bio Inc.	90	89	87	91	89	86	100	100	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	97	100	97	100	99	99	100	100	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	93	92	90	96	94	92	100	100	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	95	91	89	97	96	95	100	100	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	31	24	15	33	34	24	93	90	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	95	96	94	97	98	96	100	100	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)[d]	05FK90	Standard Diagnostics Inc. (Alere)	95	98	94	92 (99)	94	90 (99)	100	100	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	92	91	90	92	91	90	100	99	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	100	99	99	98	95	94	99	100	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	90	91	87	94	95	93	100	100	34	35	34	34	35	34	35	35
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	92	92	90	95	97	95	100	99	35	35	35	34	35	34	35	34
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	90	88	87	88	90	86	100	100	35	35	35	34 (34)	34	33 (34)	35	35
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	91	94	89	92	91	90	100	100	35	33	33	35	35	35	35	35
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	67	72	66	72	70	67	98	98	30	30	27	28	31	25	35	35
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	81	73	73	79	79	70	99	99	34	34	34	33	33	32	35	35
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	93	92	89	89	91	87	100	99	35	35	35	35	35	35	35	34
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	55	52	39	50	48	38	96	97	35	35	35	35	35	35	35	35
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	95	94	93	96	95	93	100	100	35	34	34	35	34	34	35	34
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	91	90	89	91	93	91	100	99	35	35	35	35	35	35	35	35
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	98 (98)	97	95 (98)	97	96	94	100	99	33	33 (34)	31 (34)	31	33	30	35	35
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	89	91	87	94	96	93	99	100	33	34	32	32	34	31	34 (34)	35
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	91	95	90	93	94	91	100	100	35	35	35	35	35	35	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
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	90	88	87	93	95	92	100	100	35	35	35	35	35	35	35	35
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	95	95	92	91	97	91	99 (99)	99	33	32	31	32	30	28	35	34
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	96	96	95	96	96	95	100	100	35	35	35	35	35	35	35	35
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	99	96	96	98 (99)	99	97 (99)	100	100	35	35	35	35	35	35	35	35
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	93	90	89	90	92	87	99	98	33	33	32	33	30	29	35	34
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	94 (99)	94	92 (99)	91	94	88	99	98	35	35	35	34	32 (34)	31 (34)	35	35
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	91	91	89	89	91	89	100	99	35	35	35	35	35	35	35	35
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	90	91	86	98	95	94	97	100	32	29	28	35	34	34	35	35
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	99	99	98	100	100	100	100	100	35	35	35	34	35	34	35	35
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	100	99	99	99	100	99	100	100	35	35	35	30	30	30	35	30
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v[d]	05FK120	Standard Diagnostics Inc. (Alere)	94	95	92	93	95	91	100	100	35	34	34	35	35	35	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] 2 (2%) of the 100 *P. falciparum* high parasite density dilution samples were at 5000 parasites/µL rather than 2000 parasites/µL

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

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

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																																
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	4.8	13.3	35.0	25.3	21.8	0.0	0.0	4.5	22.5	73.0	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 RDT - HRP2 band	RMSM-02571	Access Bio Inc.	11.3	14.0	24.5	21.0	29.3	0.5	1.5	4.5	10.0	83.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			42.5	45.3	12.3	0.0	0.0	3.0	8.0	48.5	36.5	4.0	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 RDT	RMPM-02571	Access Bio Inc.	1.0	9.8	39.8	26.5	23.0	0.0	0.0	3.5	16.5	80.0	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 RDT	RMPM-02591	Access Bio Ethiopia	6.3	17.3	37.5	26.0	13.0	0.0	0.0	9.0	23.0	68.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	5.3	15.0	37.5	23.3	19.0	0.0	0.0	6.5	22.0	71.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	69.5	30.3	0.3	0.0	0.0	8.5	38.5	47.5	5.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	3.5	17.5	36.8	26.8	15.5	0.0	0.0	7.5	25.0	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	7.0	17.3	37.5	27.0	11.3	0.5	0.5	11.0	25.0	63.0	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) - pLDH band			17.3	69.8	13.0	0.0	0.0	1.5	4.5	65.0	28.5	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	8.5	17.3	33.0	27.8	13.5	0.5	0.0	11.5	23.5	64.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	2.0	14.3	43.3	24.8	15.8	0.5	1.5	4.5	25.0	68.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																																
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	7.5	22.0	27.5	23.0	20.0	0.0	0.5	5.5	20.5	73.5	18.3	66.0	15.8	0.0	0.0	1.0	4.5	49.0	36.0	9.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	6.0	21.5	27.8	25.0	19.8	0.5	0.5	7.0	20.5	71.5	18.8	70.0	11.0	0.3	0.0	1.5	8.5	63.0	26.0	1.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	11.0	17.0	29.8	24.3	18.0	0.0	0.5	6.5	24.0	69.0	26.3	56.3	17.5	0.0	0.0	1.5	3.5	41.5	33.5	20.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	8.0	19.3	27.3	25.0	20.5	0.0	1.5	6.0	21.0	71.5	18.3	69.3	12.5	0.0	0.0	1.5	7.5	62.0	27.5	1.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	29.8	31.3	30.8	8.0	0.3	2.0	6.5	35.0	27.5	29.0	79.5	20.3	0.3	0.0	0.0	8.5	45.0	45.5	1.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	22.0	30.3	39.8	7.8	0.3	1.0	5.5	30.5	36.5	26.5	90.5	9.5	0.0	0.0	0.0	23.0	61.5	15.5	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	8.8	27.8	36.8	24.5	2.3	0.5	2.0	17.5	33.0	47.0	27.5	66.5	6.0	0.0	0.0	2.5	5.0	71.5	20.5	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	48.8	48.5	2.5	0.3	0.0	3.5	13.5	63.5	19.5	0.0	41.3	54.5	4.0	0.3	0.0	2.0	12.0	59.5	26.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	5.0	10.8	36.3	24.8	23.3	0.0	0.0	5.0	18.0	77.0	64.5	33.8	1.8	0.0	0.0	2.5	22.5	57.5	17.0	0.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	8.8	18.0	32.0	27.0	14.3	0.5	1.5	9.5	25.5	63.0	47.0	52.3	0.8	0.0	0.0	3.0	23.5	63.0	10.5	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	2.8	18.8	37.5	27.8	13.3	0.5	0.0	6.5	29.5	63.5	31.3	67.0	1.8	0.0	0.0	2.5	31.0	64.0	2.5	0.0	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
Pf and Pv/Pvom																																
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	7.5	22.0	36.5	27.5	6.5	0.5	0.0	12.5	35.0	52.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.0	1.0	0.0	0.0	0.0	99.0	0.5	0.5	0.0	0.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	6.8	22.0	28.8	22.3	20.3	0.0	0.0	6.5	23.0	70.5	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/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	8.5	20.3	26.8	25.3	19.3	0.0	0.5	6.5	18.5	74.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	97.0	3.0	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	5.5	15.5	32.3	28.8	18.0	1.0	1.5	7.0	23.0	67.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	98.3	1.5	0.3	0.0	0.0	100.0	0.0	0.0	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	4.0	9.3	35.8	25.0	26.0	0.0	0.0	5.0	16.5	78.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.3	0.8	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	2.0	20.0	32.8	29.8	15.5	0.0	0.0	5.0	28.0	67.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.3	0.8	0.0	0.0	0.0	99.5	0.0	0.0	0.5	0.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	8.8	25.0	34.3	26.0	6.0	1.5	2.0	12.5	33.0	51.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.8	0.3	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	6.5	18.0	36.5	24.5	14.5	1.5	0.5	9.0	29.5	59.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.8	0.3	0.0	0.0	0.0	98.5	0.0	1.5	0.0	0.0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	9.5	21.0	29.5	28.0	12.0	0.5	1.5	14.0	26.0	58.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	99.5	0.5	0.0	0.0	0.0	99.5	0.5	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	6.5	27.3	36.5	23.0	6.8	1.5	0.5	15.0	31.0	52.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	62.8	37.3	0.0	0.0	0.0	80.0	20.0	0.0	0.0	0.0
Pan only																																
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.5	23.0	42.0	26.5	8.0	0.0	0.0	6.0	25.0	69.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.5	19.8	41.8	29.8	8.3	0.0	0.0	5.0	25.5	69.5	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																																
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	6.3	15.8	34.8	24.3	19.0	0.5	0.0	7.5	24.0	68.0	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/P.f/P.v - Pf-LDH band			27.3	63.0	9.8	0.0	0.0	1.0	6.0	63.0	29.0	1.0	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/P.f/P.v - Pv-LDH band			NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	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

NA, not applicable

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

[a] Denotes no visible band

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

[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																																
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - HRP2 band	RMSM-02571	Access Bio Inc.	99.3	0.7	0.0	0.0	0.0	97.1	1.4	1.4	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			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
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio 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	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	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
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	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
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	95.0	5.0	0.0	0.0	0.0	87.1	12.9	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
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	98.6	1.4	0.0	0.0	0.0	95.7	4.3	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	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) - pLDH band			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
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	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
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	100.0	0.0	0.0	0.0	0.0	98.6	0.0	0.0	0.0	1.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and pan																																
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.7	12.1	62.1	24.3	0.7	0.0	0.0	0.0	18.6	81.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	100.0	0.0	0.0	0.0	0.0	98.6	0.0	0.0	0.0	1.4	0.7	12.9	75.0	10.7	0.7	1.4	0.0	2.9	44.3	51.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.7	18.6	71.4	9.3	0.0	0.0	0.0	1.4	17.1	81.4	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	99.3	0.0	0.0	0.7	0.0	100.0	0.0	0.0	0.0	0.0	1.4	15.0	77.1	5.7	0.7	0.0	0.0	8.6	28.6	62.9	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	99.3	0.0	0.0	0.7	0.0	100.0	0.0	0.0	0.0	0.0	14.3	62.1	23.6	0.0	0.0	0.0	0.0	34.3	58.6	7.1	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
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	4.3	42.9	51.4	1.4	0.0	0.0	0.0	8.6	55.7	35.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	100.0	0.0	0.0	0.0	0.0	98.6	0.0	1.4	0.0	0.0	0.0	19.3	79.3	1.4	0.0	0.0	0.0	0.0	55.7	44.3	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	10.7	79.3	10.0	0.0	0.0	0.0	1.4	48.6	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	99.3	0.7	0.0	0.0	0.0	98.6	1.4	0.0	0.0	0.0	0.7	33.6	65.0	0.0	0.7	0.0	0.0	4.3	45.7	50.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	0.0	0.7	71.4	27.1	0.7	0.0	0.0	0.0	14.3	85.7	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
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	99.3	0.7	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	6.4	47.9	45.7	0.0	0.0	0.0	0.0	35.7	54.3	10.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf and Pv/Pvom																																
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories 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	5.0	48.6	45.7	0.7	0.0	1.4	0.0	21.4	62.9	14.3
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	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	14.3	62.1	22.9	0.7	0.0	0.0	0.0	15.7	84.3
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	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	32.1	64.3	2.9	0.7	0.0	0.0	4.3	48.6	47.1
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	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	9.3	48.6	40.0	2.1	0.0	1.4	0.0	32.9	54.3	11.4
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	100.0	0.0	0.0	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	2.1	67.1	30.7	0.0	0.0	0.0	0.0	18.6	81.4
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	99.3	0.0	0.7	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.0	0.7	72.1	27.1	0.0	0.0	0.0	0.0	10.0	90.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	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	7.9	62.1	28.6	1.4	0.0	1.4	0.0	32.9	51.4	14.3
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	99.3	0.0	0.7	0.0	0.0	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	2.1	30.0	67.1	0.7	0.0	0.0	0.0	7.1	51.4	41.4
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	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	1.4	66.4	31.4	0.7	0.0	0.0	0.0	8.6	91.4
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	87.1	12.9	0.0	0.0	0.0	97.1	2.9	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.1	52.1	40.0	0.7	0.0	0.0	1.4	54.3	42.9	1.4
Pan only																																
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.7	16.4	63.6	18.6	0.7	0.0	0.0	0.0	21.4	78.6	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	7.1	13.6	60.0	17.1	2.1	7.1	0.0	2.9	14.3	75.7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																																
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	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/P.f/P.v - Pf-LDH band			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/P.f/P.v - Pv-LDH band			NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	0.7	23.6	75.7	0.0	0.0	0.0	0.0	4.3	52.9	42.9

NA, not applicable

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

[a] Denotes no visible band

[b] Calculations include invalid tests

Table A4.4: Phase-2 *P. falciparum* test line false-positive rates for wild-type *P. vivax* samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	Manufacturer	*P. vivax* samples (n=35)					
			200 parasites/µL False-positive Pf infection[a] (%)			2000 parasites/µL False-positive Pf infection[a] (%)		
			Lot 1 (n=70)	Lot 2 (n=70)	Overall (n=140)	Lot 1 (n=35)	Lot 2 (n=35)	Overall (n=70)
Pf only								
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - HRP2 band	RMSM-02571	Access Bio Inc.	0.0	1.4	0.7	2.9	2.9	2.9
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - Pf-LDH band			1.4	0.0	0.7	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	0.0	0.0	0.0	2.9	0.0	1.4
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	7.1	2.9	5.0	17.1	8.6	12.9
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	2.9	0.0	1.4	2.9	5.7	4.3
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - Pf-LDH band			0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	0.0	0.0 (69)	0.0 (139)	0.0	2.9	1.4
Pf and pan								
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	1.4	0.0	0.7	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	2.9	1.4
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0.0	0 .0(69)	0.0 (139)	0.0	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	1.4	0.0	0.7	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0.0	1.4	0.7	0.0	0.0	0.0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	2.9	1.4
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	1.4	0.0	0.7	0.0	2.9	1.4
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	1.4 (69)	0.0	0.7 (139)	0.0	0.0	0.0
Pf and Pv/Pvom								
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	0.0	0.0	0.0	0 (34)	0.0	0.0 (69)
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0	0.0	0.0	2.9	1.4
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	1.4	0.0	0.7	0.0	0.0	0.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	0.0	0.0	0.0	2.9	1.4

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)
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0	1.4 (69)	0.7 (139)	0.0	0.0	0.0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	5.7	20.0	12.9	2.9	2.9	2.9
Pan only								
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv								
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/P.f/P.v - Pf-LDH band			0.0	0.0	0.0	0.0	0.0	0.0

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

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

Table A4.5: Phase 2 pan (or *P. vivax*) test line false-positive rate for non-*P. falciparum* infection on phase-2 wild-type *P. falciparum* samples at low (200) and high (2000) parasite density (parasites/µL)

Product	Product code	Manufacturer	*P. falciparum* samples (n=100)					
			200 parasites/µL False-positive non-Pf infection (%)			2000[a] parasites/µL False-positive non-Pf infection (%)		
			Lot 1 (n=200)	Lot 2 (n=200)	Overall (n=400)	Lot 1 (n=100)	Lot 2 (n=100)	Overall (n=200)
Pf and Pan								
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	4.0	2.0	3.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	2.0	2.0	2.0	0.0	1.0	0.5
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	2.5	1.5	2.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	3.5	2.5	3.0	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	1.0	0.0	0.5	2.0	2.0	2.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	1.0	0.0	0.5	0.0	0.0	0.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	1.5	1.0	1.3	0.0	1.0	0.5
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	7.0	13.5	10.3	2.0	1.0	1.5
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	1.0	0.5
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	0.5 (198)	0.5	0.5 (398)	0.0	1.0	0.5
Pf and Pv/Pvom								
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	1.0	1.0	1.0	2.0	0.0	1.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	1.0	5.0	3.0	0.0	1.0	0.5
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	1.0	2.5	1.8	0.0 (99)	0.0	0.0 (199)
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1.0	0.5	0.8	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	1.5	0.0 (199)	0.8 (399)	1.0	0.0	0.5
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	0.5	0.3	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0 (199)	0.5	0.3 (399)	0.0	3.0	1.5
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.5	0.5	0.5	1.0	0.0	0.5
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	34.0	40.5	37.3	18.0	22.0	20.0
Pan only								
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv								
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0

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

[a] 2 (2%) 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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
Pf only											
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	0.0	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 RDT - HRP2 band	RMSM-02571	Access Bio Inc.	1.0	0.0	0.5	0.0	2.4	1.2	1.9	0.0	0.9
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	13.0	11.1	12.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	3.7	5.6	4.6
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II) - HRP2 band[d]	RK MAL 025-25	Advy Chemical Pvt. Ltd.	33.3 (39)	82.5 (40)	58.2 (79)	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH and HRP-II) - pLDH band[d]	RK MAL 025-25	Advy Chemical Pvt. Ltd.	28.2 (39)	70.0 (40)	49.4 (79)	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	9.6	1.9	5.8	2.4	4.8	3.6	16.7	9.3	13.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	3.8	2.9 (103)	3.4 (207)	2.4	0.0	1.2	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0	3.7	3.7	3.7
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan											
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.9
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0.0	1.9	1.0	0.0	0.0	0.0	25.9	25.9	25.9
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.0	0.9
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	1.0	0.0	0.5	0.0	0.0	0.0	0.0	5.6	2.8
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	1.0	1.0	1.0	4.8	7.3 (41)	6.0 (83)	0.0	0.0	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	1.9	1.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	4.8	1.9	3.4	4.8	0.0	2.4	11.1	7.4	9.3
Pf and Pv/Pvom											
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	0.0	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-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.0	0.9
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., 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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	1.0	0.0	0.5	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0.0	1.0	0.5	0.0	0.0	0.0	0.0	1.9	0.9
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	1.0	1.0	1.0	0.0	0.0	0.0	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0 (100)	0.0 (101)	0.0 (201)	0.0	0.0	0.0	0.0	1.9	0.9
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	7.7	15.4	11.5	7.1	11.9	9.5	16.7	13.0	14.8
Pan only											
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv											
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0	3.7	3.7	3.7
SD BIOLINE Malaria Ag P.f/P.f/P.v - pLDH band			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

[d] Product had high false positive rates on 20 clean negative samples from Phase 1. Therefore, was excluded from Phase 2

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=8)	Lot 2 (n=8)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=2)	Lot 2 (n=2)	Lot 1 (n=20)	Lot 2 (n=20)
Pf only										
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 band	RMSM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	5.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	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 RDT	RMPM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	0.0	12.5	0.0	8.3	0.0	0.0	5.0	0.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	0.0	0.0	0.0	0.0	0.0	0.0	5.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	10.0	15.8 (19)
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	12.5	0.0	8.3	0.0	0.0	0.0	0.0	0.0
Pf and Pv/Pvom										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Table A4.7 *(continued)*

Product	Product code	Manufacturer	Percentage of false positives for *Plasmodium* spp. by infectious pathogen							
			Chagas		Dengue		Leishmaniasis		Schistosomiasis	
			Lot 1 (n=8)	Lot 2 (n=8)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=2)	Lot 2 (n=2)	Lot 1 (n=20)	Lot 2 (n=20)
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	25.0	37.5	0.0	16.7	0.0	0.0	5.0	0.0
Pan only										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv										
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/P.f/P.v - 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 A4.8: 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=4)	Lot 2 (n=4)	Lot 1 (n=28)	Lot 2 (n=28)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)
Pf only										
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 band	RMSM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	8.3	0.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			25.0	50.0	0.0	0.0	50.0	33.3	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	16.7	25.0	0.0	0.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	50.0	0.0	7.1	10.7	16.7	8.3	30.0	10.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	50.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band			0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Pf and pan										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	0.0	0.0	3.6	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	50.0	50.0	7.1	3.6	83.3	91.7	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0.0	0.0	0.0	0.0	8.3	0.0	0.0	0.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	0.0	25.0	0.0	0.0	0.0	8.3	0.0	10.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	25.0	25.0	7.1	3.6	16.7	8.3	10.0	10.0
Pf and Pv/Pvom										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0.0	0.0	3.6	0.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0.0	0.0	0.0	0.0	0.0	8.3	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=4)	Lot 2 (n=4)	Lot 1 (n=28)	Lot 2 (n=28)	Lot 1 (n=12)	Lot 2 (n=12)	Lot 1 (n=10)	Lot 2 (n=10)
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0	0.0	0.0	3.6	0.0	0.0	0.0	0.0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	25.0	0.0	14.3	14.3	8.3	8.3	30.0	20.0
Pan only										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv										
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	50.0	50.0	0.0	0.0	0.0	0.0	0.0	0.0
SD BIOLINE Malaria Ag P.f/P.f/P.v - 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 A4.9: 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 non-Pf test lines on "clean" negative samples[a]			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=104)	Lot 2 (n=104)	Overall (n=208)	Lot 1 (n=42)	Lot 2 (n=42)	Overall (n=84)	Lot 1 (n=54)	Lot 2 (n=54)	Overall (n=108)
Pf and pan											
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	9.3	11.1	10.2
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0.0	0.0	0.0	0.0	0.0	0.0	7.4	3.7	5.6
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	5.6	1.9	3.7
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0.0	0.0	0.0	2.4	0.0	1.2	7.4	5.6	6.5
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0.0	0.0	0.0	0.0	0.0	0.0	3.7	3.7	3.7
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	1.9	1.9	1.9
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	1.0	0.5	2.4	0.0 (41)	1.2 (83)	0.0	0.0	0.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0.0	1.9	1.0	0.0	2.4	1.2	0.0	1.9	0.9
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	1.0	0.0	0.5	2.4	0.0	1.2	11.1	7.4	9.3
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	12.5	7.7	10.1	7.1	14.3	10.7	33.3	46.3	39.8
Pf and Pv/Pvom											
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	0.0	0.0	0.0	0.0	0.0	0.0	1.9	0.0	0.9
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	0.0	0.0	0.0	0.0	0.0	0.0	5.6	7.4	6.5
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0.0	0.0	0.0	2.4	0.0	1.2	11.1	9.3	10.2
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0.0	0.0	0.0	4.8	0.0	2.4	7.4	7.4	7.4
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0.0	0.0	0.0	2.4	0.0	1.2	3.7	0.0	1.9
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	1.0	0.0	0.5	0.0	4.8	2.4	11.1	14.8	13.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0.0	1.9	1.0	0.0	0.0	0.0	1.9	0.0	0.9
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0.0 (100)	0.0 (101)	0.0 (201)	0.0	0.0	0.0	7.4	5.6	6.5
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	26.0	35.6	30.8	19.0	38.1	28.6	44.4	50.0	47.2
Pan only											
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	16.3	1.9	9.1	2.4	4.8	3.6	20.4	18.5	19.4
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	3.8	6.7	5.3	7.1	2.4	4.8	20.4	16.7	18.5
Pf, Pf and Pv											
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

NA, not applicable

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

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

[b] See Table A4.7 for details

[c] See Table A4.8 for details

Table A4.10: Heat stability testing results for *P. falciparum* test line on a *P. falciparum* sample at low parasite density (200 parasites/µL).
Number of positive tests 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																										
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio Inc.	15	0	3.1	15	0	3.0	15	0	3.2	15	0	3.0	15	0	3.5	15	0	3.1	15	0	3.1	15	0	3.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - HRP2 band	RMSM-02571	Access Bio Inc.	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.3	15	0	3.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - pLDH band			0	0	0.0	0	0	0.0	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 Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	15	0	3.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.8	15	0	2.9	15	0	3.0	15	0	3.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	15	0	2.9	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.1
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	15	0	1.0	6	0	1.0	2	0	1.0	15	0	1.0	1	0	1.0	9	0	1.0	11	0	1.0	10	0	1.0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0	15	0	3.0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band			15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0
Pf and pan																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.5	15	0	3.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.0	15	0	2.9	15	0	3.0	15	0	3.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.7	15	0	3.0	15	0	3.0	15	0	3.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	1.9	15	0	2.0	15	0	1.9	15	0	2.0
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	2.0	15	0	2.0	15	0	2.0	15	0	2.0	15	0	2.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.8	15	0	2.0	15	0	3.0	15	0	3.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	13	0	1.0	6	0	1.0	8	0	1.0	14	0	1.0	15	0	1.0	13	0	1.0	12	0	1.0	15	0	1.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	15	0	3.0	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.1
VISITECT® Malaria Pf/Pan	OD326	Omega Diagnostics Ltd.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
Pf and Pv/Pvom																										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	15	0	2.9	15	0	2.9	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.2	15	0	3.0	15	0	3.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.3	15	0	3.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	2.9	15	0	3.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	15	0	3.2	15	0	3.0	15	0	3.1	15	0	3.0	15	0	3.5	15	0	3.1	15	0	3.0	15	0	4.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	15	0	2.9	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.8	15	0	2.9	15	0	2.9	15	0	3.0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	15	0	2.8	15	0	3.0	15	0	3.0	15	0	2.9	15	0	3.2	15	0	2.9	15	0	3.2	15	0	3.3
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	15	0	2.9	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.7	14	1	2.9	15	0	3.0	15	0	3.1

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
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	15	0	2.8	15	0	3.0	15	0	2.8	15	0	3.0	14	1	2.2	14	1	2.0	15	0	2.9	15	0	3.0
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																										
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	15	0	3.1	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	3.0
SD BIOLINE Malaria Ag P.f/P.f/P.v - pLDH band			15	0	1.0	15	0	1.0	14	0	1.0	14	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0

ND, not determined NA, not applicable
Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species

Table A4.10a: Heat stability testing results for pan test line of combination and pan-only RDTs on a *P. falciparum* sample at low parasite density (200 parasites/µL). Number of positive tests 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																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	15	0	1.0	15	0	1.0	14	0	1.0	14	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	14	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	13	0	1.0	15	0	1.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	7	0	1.0	14	0	1.0	11	0	1.0	15	0	1.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	15	0	1.0	15	0	1.0	15	0	1.0	12	0	1.0	10	0	1.0	15	0	1.0	15	0	1.0	15	0	1.1
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	8	0	1.0	0	0	0.0	0	0	0.0	0	0	0.0	2	0	1.0	0	0	0.0	0	0	0.0	0	0	0.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	9	0	1.0	0	0	0.0	13	0	1.0	0	0	0.0	15	0	1.0	10	0	1.0	8	0	1.0	7	0	1.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	14	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	15	0	1.0	14	0	1.0	15	0	1.0	15	0	1.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	13	0	1.0	3	0	1.0	10	0	1.0	13	0	1.0	15	0	1.0	14	0	1.0	13	0	1.0	15	0	1.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	15	0	1.0	15	0	1.0	15	0	1.0	8	0	1.0	7	0	1.0	15	0	1.0	7	0	1.0	1	0	1.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	5	0	1.0	0	0	0.0	1	0	1.0	14	0	1.0	15	0	1.0	13	0	1.0	6	0	1.0	11	0	1.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	7	0	1.0	7	0	1.0	9	0	1.0	12	0	1.0	11	0	1.0	10	0	1.0	8	0	1.0	0	0	0.0
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	15	0	2.7	15	0	3.0	15	0	3.0	15	0	3.0	15	0	3.0	15	0	2.9	15	0	2.9	15	0	3.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	15	0	2.9	15	0	3.0	15	0	2.9	15	0	2.9	15	0	2.7	15	0	2.8	15	0	3.0	15	0	2.9

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).
Number of positive tests 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																										
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 band	RMSM-02571	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 RDT - pLDH band			4	0	1.0	4	0	1.0	5	0	1.0	5	0	1.0	0	0	ND	2	0	1.0	0	0	ND	2	0	1.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio Inc.	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	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	3.8	5	0	4.0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	5	0	1.8	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	1.8
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	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) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	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) - pLDH band			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
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	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
VISITECT® Malaria Pf	OD336	Omega Diagnostics 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
Pf and pan																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	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/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	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/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	3.8	5	0	4.0	5	0	4.0	5	0	4.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	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
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	5	0	4.0	5	0	4.0	5	0	3.0	5	0	3.4	5	0	3.0	5	0	3.0	5	0	3.2	5	0	4.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	5	0	4.0	5	0	4.0	5	0	3.6	5	0	3.4	5	0	4.0	5	0	3.6	5	0	4.0	5	0	4.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-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
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	5	0	2.0	4	0	2.0	5	0	1.8	5	0	2.0	5	0	2.0	5	0	1.4	5	0	2.0	5	0	2.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	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
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics 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
Pf and Pv/Pvom																										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	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
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	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/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	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
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises 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
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	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	5	0	4.0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	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
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics 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

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
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																										
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0	5	0	4.0
SD BIOLINE Malaria Ag P.f/P.f/P.v - pLDH band			5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.2	5	0	2.0	5	0	2.0	5	0	2.0

ND, not determined NA, not applicable
Pf, *Plasmodium falciparum* Pv, *Plasmodium vivax* pan, *Plasmodium* species

Table A4.11a: Heat stability testing results for pan test line of combination and pan-only RDTs on a *P. falciparum* sample at high parasite density (2000 parasites/µL). Number of positive tests 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																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	5	0	2.0	5	0	2.4	5	0	2.2	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.4
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.6
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	5	0	3.0	5	0	3.0	5	0	2.2	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, 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	2.2
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	5	0	2.0	5	0	1.0	5	0	1.0	5	0	1.0	5	0	1.6	5	0	2.0	5	0	1.0	5	0	1.6
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	5	0	1.4	5	0	1.6	5	0	1.6	5	0	2.0	5	0	2.0	5	0	1.4	5	0	2.0	5	0	1.8
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	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
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	5	0	2.0	4	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
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.8	5	0	2.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	5	0	2.0	5	0	2.0	5	0	2.0	5	0	2.0	5	0	1.0	5	0	2.0	5	0	2.0	5	0	1.0
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	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
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	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

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.
Number of positive tests 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																		
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 band	RMSM-02571	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 RDT - pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	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 RDT	RMPM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and pan																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Table A4.12 *(continued)*

Product	Product code	Manufacturer	Baseline testing				35°C				45°C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	0	0	0	1	0	0	0	0	0	0	3	0	0	0
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f/P.f/P.v - 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 A4.12a: Heat stability testing results for pan or *P. vivax* test line of combination and pan-only RDTs on parasite-negative samples. Number of positive tests 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																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	3	0	2	0	0	0	3	0	0	0	0	0	1	0	0	0
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	0	0	0	1	0	0	0	0	0	0	3	0	0	0
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	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). Number of positive tests 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																		
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 band	RMSM-02571	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 RDT - pLDH band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	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 RDT	RMPM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	1	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 Band	05FK90	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH Band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and pan																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(continued)

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

Product	Product code	Manufacturer	Baseline testing				35°C				45°C				Room temperature			
			Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)		Lot 1 (n=4)		Lot 2 (n=4)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 Band	05FK120	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f/P.f/P.v - 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 A4.14: Heat stability testing results for *P. falciparum* test line on *P. vivax* samples at high parasite density (2000 parasites/µL). Number of positive tests 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																		
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	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 RDT - HRP2 Band	RMSM-02571	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 RDT - pLDH Band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	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 RDT	RMPM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 Band	05FK90	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - pLDH Band			0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf	0D336	Omega Diagnostics Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and pan																		
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
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
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pf and Pv/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

(continued)

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

Product	Product code	Manufacturer	Baseline testing				35°C				45°C				Room temperature			
			Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)		Lot 1 (n=2)		Lot 2 (n=2)	
			No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid	No. positive	No. invalid
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Pan only																		
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 Band	05FK120	Standard Diagnostics Inc. (Alere)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
SD BIOLINE Malaria Ag P.f/P.f/P.v - 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 A4.15: Heat stability testing results for *P. vivax* test line on *P. falciparum* samples at low parasite density (200 parasites/µL).
Number of positive tests 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/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	7	0	5	0	4	0	0	1	0	1	5	0	0	0
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	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).
Number of positive tests 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/Pvom																		
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	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-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	0	0	1	0	4	0	2	0	1	0	0	0	2	0	1	0
Pf, Pf and Pv																		
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	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 and pan-only tests on a *P. vivax* sample at low parasite density (200 parasites/µL). Number of positive tests 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																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	4	0	1.8	4	0	2.0	4	0	2.3	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	3	1	1.7	4	0	1.5	4	0	2.0	4	0	2.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0	4	0	1.5
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	4	0	1.3	4	0	1.0	4	0	1.0	4	0	1.3	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	4	0	2.0	4	0	1.8	4	0	1.8	4	0	2.0	4	0	1.5	4	0	2.0	4	0	2.0	4	0	2.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0	4	0	2.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	4	0	2.0	4	0	2.0	4	0	2.0	4	0	3.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	1.3	4	0	1.3	4	0	2.0	4	0	1.0
Pf and Pv/Pvom																										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	4	0	2.0	4	0	1.0	4	0	1.0	4	0	2.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	4	0	1.8	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
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	4	0	1.8	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.0	4	0	1.8	4	0	2.0	4	0	2.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	4	0	1.5	4	0	2.0	4	0	1.5	4	0	1.8	4	0	1.0	4	0	1.0	4	0	2.0	4	0	1.3
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	4	0	2.3	4	0	3.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	4	0	1.5	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.0	4	0	1.8
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.5	4	0	2.0	4	0	1.5
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	4	0	2.3	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
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	4	0	1.5	4	0	1.0	4	0	1.3	4	0	1.8	3	0	1.0	3	0	1.0	4	0	1.3	4	0	1.0
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	4	0	2.0	4	0	2.3	4	0	2.3	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0	4	0	2.0	4	0	2.0
Pf, Pf and Pv																										
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.8	4	0	2.0	4	0	2.0	4	0	2.0	4	0	1.5

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 and pan-only tests on a *P. vivax* sample at high parasite density (2000 parasites/µL). Number of positive tests 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	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																										
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio Inc.	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	4.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	2	0	3.5	2	0	4.0	2	0	3.5	2	0	4.0	2	0	4.0	2	0	3.0	2	0	4.0	2	0	3.0
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio Inc.	2	0	4.0	2	0	3.0	2	0	4.0	2	0	3.5	2	0	3.5	2	0	3.5	2	0	4.0	2	0	4.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	2	0	4.0	2	0	4.0	2	0	3.5	2	0	3.0	2	0	3.5	2	0	3.5	2	0	3.5	2	0	4.0
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	3.0
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	2	0	3.0	2	0	4.0	2	0	3.0	2	0	3.0	2	0	3.5	2	0	4.0	2	0	3.5	2	0	3.0
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt. Ltd.	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	3.5	2	0	4.0
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt. Ltd.	2	0	3.5	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	4.0	2	0	3.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	2	0	4.0	2	0	4.0	2	0	4.0	2	0	3.0	2	0	3.0	2	0	3.5	2	0	4.0	2	0	4.0
STANDARD Q Malaria P.f / Pan Ag Test	09MAL30B	SD Biosensor	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	4.0
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	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/Pvom																										
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	Aspen Laboratories Pvt. Ltd.	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.0	2	0	2.5	2	0	3.0	2	0	3.0
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio Inc.	2	0	4.0	2	0	4.0	2	0	4.0	2	0	4.0	2	0	4.0	2	0	3.5	2	0	3.5	2	0	4.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio Inc.	2	0	3.0	2	0	3.0	2	0	3.5	1	1	3.0	2	0	3.0	2	0	3.5	2	0	3.5	2	0	4.0
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	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
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	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	4.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	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
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises Pvt. Ltd.	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
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	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	3.5	2	0	3.0
STANDARD Q Malaria P.f /P.v Ag Test	09MAL20B	SD Biosensor	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	4.0
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	2	0	3.0	2	0	2.0	2	0	3.0	2	0	3.0	2	0	2.0	2	0	2.0	2	0	3.0	2	0	2.5
Pan only																										
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	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	4.0
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	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	3.5
Pf, Pf and Pv																										
SD BIOLINE Malaria Ag P.f/P.f/P.v	05FK120	Standard Diagnostics Inc. (Alere)	2	0	3.5	2	0	3.0	2	0	3.5	2	0	3.0	2	0	3.0	2	0	3.0	2	0	3.5	2	0	3.5

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

Table A4.19: Lot variation in *P. falciparum* positive results against HRP2-negative *P. falciparum* samples

Product	Product code	Manufacturer	HRP2-ve / HRP3-ve *P. falciparum* samples (n=18) Total positive results[a] returned						HRP2-ve / HRP3 +ve *P. falciparum* samples (n=22) Total positive results[a] returned					
			Lot 1			Lot 2			Lot 1			Lot 2		
			Test 1	Test 2	No. positive agreements[b] (max=18)	Test 1	Test 2	No. positive agreements[c] (max=18)	Test 1	Test 2	No. positive agreements[b] (max=22)	Test 1	Test 2	No. positive agreements[b] (max=22)
Detect Pf using Pf-LDH alone or in combination														
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT[c]	RMSM-02571	Access Bio, Inc.	7	11	3	13	15	13	12	13	7	12	15	9
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio, Inc.	17	18	17	13	14	13	15	17	13	22	20	20
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	11	14	9	11	8	8	14	14	8	15	13	10
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio, Inc.	2	6	2	2	0	0	0	1	0	4	5	3
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	9	12	6	11	12	10	12	16	8	13	15	12
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	8	11	4	13	14	13	11	12	6	11	11	8
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt Ltd.	8	12	5	11	11	11	9	14	6	9	6	5
SD BIOLINE Malaria Ag P.f (HRP2/pLDH)[c]	05FK90	Standard Diagnostics Inc. (Alere)	15	15	12	14	13	13	9	16	9	15	12	12
SD BIOLINE Malaria Ag P.f/P.f/P.v[c]	05FK120	Standard Diagnostics Inc. (Alere)	14	11	8	12	11	11	5	14	4	11	11	9
Detect Pf using pan-pLDH only														
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	18	18	18	17	16	16	21	21	20	22	22	22
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	17	17	16	16	18	16	21	21	21	20	21	19
Detect Pf using HRP2 only (Pf only tests)														
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio, Inc.	0	0	0	0	0	0	17	13	11	15	11	10
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	4	3	1	3	1	1	20	15	15	9	10	7
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	0	0	0	0	0	0	18	17	17	16	16	14
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	5	2	1	1	1	0	21	20	20	20	20	19
Detect Pf using HRP2 only (Pf/pan, Pf/Pv and Pf/VOM tests)														
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	ASPEN LABORATORIES PVT.LTD	0	1	0	0	0	0	19	18	18	16	15	13
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio, Inc.	0	0	0	0	0	0	6	7	4	5	4	4
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	0	1	0	0	0	0	8	7	7	10	5	5
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio, Inc.	0	0	0	0	0	0	8	6	6	4	5	4
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio, Inc.	0	0	0	0	0	0	4	4	4	4	4	4
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	0	0	0	0	0	0	8	10	8	8	5	5
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	0	0	0	0	0	0	4	2	2	2	1	1
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	0	0	0	0	0	0	15	14	13	16	13	11
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	0	0	0	0	0	0	2	1	1	2	0	0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	0	0	0	0	0	0	11	6	5	10	10	7
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises pvt ltd	0	1	0	0	1	0	15	18	15	18	16	16
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	7	2	1	1	5	0	5	3	1	3	7	1
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt Ltd.	0	0	0	2	0	0	10	12	8	7	6	3
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	1 (17)	1	0 (17)	0	0	0	19	18	17	18	16	13

Table A4.19: Lot variation in *P. falciparum* positive results against HRP2-negative *P. falciparum* samples *(continued)*

Product	Product code	Manufacturer	HRP2-ve / HRP3-ve *P. falciparum* samples (n=18) Total positive results[a] returned						HRP2-ve / HRP3 +ve *P. falciparum* samples (n=22) Total positive results[a] returned					
			Lot 1			Lot 2			Lot 1			Lot 2		
			Test 1	Test 2	No. positive agreements[b] (max=18)	Test 1	Test 2	No. positive agreements[c] (max=18)	Test 1	Test 2	No. positive agreements[b] (max=22)	Test 1	Test 2	No. positive agreements[b] (max=22)
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	0	0	0	0	0	0	0	0	0	1	0	0
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	0	3	0	0	0	0	17	18	16	13	14	10
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	0	0	0	0	0	0	18	17	17	17	15	14
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	4	1	1	0	1	0	18	21	18	18	17	14
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	3	6	1	4	2	1	14	16	13	16	14	11

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

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

Table A4.20: Distribution of test band intensity scores (0–4) against HRP2-negative *P. falciparum* samples

Product	Product code	Manufacturer	Percentage distribution of Pf test band intensity[b] (n=160)					Percentage distribution of pan test band intensity[b] (n=160)					Percentage distribution of Pv test band intensity[b] (n=160)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Detect Pf using Pf-LDH alone or in combination																	
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - HRP2 band	RMSM-02571	Access Bio, Inc.	93.1	2.5	4.4	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-line RDT - Pf-LDH band			38.8	47.5	13.1	0.6	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02571	Access Bio, Inc.	15.0	56.9	28.1	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM-02591	Access Bio Ethiopia	37.5	45.6	16.9	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-02571	Access Bio, Inc.	87.5	12.5	0.0	0.0	0.0	45.6	40.0	13.8	0.6	0.0	NA	NA	NA	NA	NA
careUS™ Malaria Combo Pf (HRP2/pLDH) Ag	RMP-M02582	WELLS BIO, INC	37.5	45.6	16.9	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
EzDx Malaria Pf Rapid malaria Antigen detection test (pLDH)	RK MAL 024-25	Advy Chemical Pvt. Ltd.	43.1	54.4	2.5	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
MERISCREEN Malaria pLDH Ag	MVLRPD-02	Meril Diagnostics Pvt Ltd.	50.0	46.3	3.8	0.0	0.0	32.5	59.4	8.1	0.0	0.0	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - HRP2 band	05FK90	Standard Diagnostics Inc. (Alere)	98.8	1.3	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f (HRP2/pLDH) - Pf-LDH band			31.9	49.4	18.8	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f/P.f/P.v - HRP2 band	05FK120	Standard Diagnostics Inc. (Alere)	100.0	0.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f/P.f/P.v - Pf-LDH band			44.4	41.3	14.4	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
SD BIOLINE Malaria Ag P.f/P.f/P.v - Pv-LDH band			44.4	41.3	14.4	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
Detect Pf using pan-pLDH only																	
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM-02591	Access Bio Ethiopia	NA	NA	NA	NA	NA	3.1	45.6	42.5	8.8	0.0	NA	NA	NA	NA	NA
careUS™ Malaria PAN (pLDH) Ag	RMN-M02582	WELLS BIO, INC	NA	NA	NA	NA	NA	5.6	43.1	45.6	5.0	0.6	NA	NA	NA	NA	NA
Detect Pf using HRP2 only (Pf only tests)																	
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-02571	Access Bio, Inc.	65.0	26.9	8.1	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Paracheck Pf® Rapid Test for Pf Malaria (Ver. 3)	302030025	Orchid Biomedical Systems (Tulip Group)	59.4	37.5	3.1	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f Ag Test	09MAL10B	SD Biosensor	58.1	30.0	11.9	0.0	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
VISITECT® Malaria Pf	OD336	Omega Diagnostics Ltd.	43.8	33.1	22.5	0.6	0.0	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Detect Pf using HRP2 only (Pf/pan, Pf/Pv and Pf/VOM tests)																	
Aspen® Mal (Ag Pf/Pv) Rapid Card Test	AS1550E	ASPEN LABORATORIES PVT.LTD	56.9	31.3	11.9	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02571	Access Bio, Inc.	86.3	13.8	0.0	0.0	0.0	30.6	51.3	18.1	0.0	0.0	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag Combo RDT	RMRM-02591	Access Bio Ethiopia	80.6	17.5	1.9	0.0	0.0	21.3	64.4	14.4	0.0	0.0	NA	NA	NA	NA	NA
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-02571	Access Bio, Inc.	85.6	14.4	0.0	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
CareStart™ Malaria Pf/VOM (HRP2/pLDH) Ag Combo RDT	RMWM-02571	Access Bio, Inc.	90.0	10.0	0.0	0.0	0.0	NA	NA	NA	NA	NA	98.8	1.3	0.0	0.0	0.0
careUS™ Malaria Combo Pf/PAN (HRP2/pLDH) Ag	RMR-M02582	WELLS BIO, INC	80.6	17.5	1.9	0.0	0.0	27.5	56.9	15.6	0.0	0.0	NA	NA	NA	NA	NA
Ecotest Malaria P.f/Pan Rapid Test Device	MAL-W23M	Assure Tech (Hangzhou)	94.4	5.6	0.0	0.0	0.0	83.8	15.6	0.6	0.0	0.0	NA	NA	NA	NA	NA
EGENS Malaria Pv/Pf Test Cassette	MAL-W23M (p.f/p.v)	Nantong Egens Biotechnology Co., Ltd.	63.8	26.3	9.4	0.6	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
FalciVax™ Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	96.9	3.1	0.0	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
First Response® Malaria Ag. P.f./P.v. Card test	PI19FRC25	Premier Medical Corporation Private Ltd.	76.9	18.1	5.0	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0
Karwa® Mal (Ag Pf/Pv) Rapid Card Test	KW 1550E	Karwa Enterprises pvt ltd	56.9	33.8	9.4	0.0	0.0	NA	NA	NA	NA	NA	100.0	0.0	0.0	0.0	0.0

Table A4.20: Distribution of test band intensity scores (0–4) against HRP2-negative *P. falciparum* samples *(continued)*

Product	Product code	Manufacturer	Percentage distribution of Pf test band intensity[b] (n=160)					Percentage distribution of pan test band intensity[b] (n=160)					Percentage distribution of Pv test band intensity[b] (n=160)				
			0[a]	1	2	3	4	0[a]	1	2	3	4	0[a]	1	2	3	4
Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	79.4	20.6	0.0	0.0	0.0	77.5	22.5	0.0	0.0	0.0	NA	NA	NA	NA	NA
MERISCREEN Malaria Pf/Pan Ag	MHLRPD-02	Meril Diagnostics Pvt Ltd.	76.9	21.3	1.9	0.0	0.0	29.4	56.9	13.8	0.0	0.0	NA	NA	NA	NA	NA
Necviparum One Step Malaria P.f./P.v. Antigen Test	MAGDR	Nectar Lifesciences Limited	54.4	29.4	16.3	0.0	0.0	NA	NA	NA	NA	NA	99.4	0.6	0.0	0.0	0.0
Parascreen® Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	99.4	0.6	0.0	0.0	0.0	48.8	48.1	3.1	0.0	0.0	NA	NA	NA	NA	NA
STANDARD Q Malaria P.f/P.v Ag Test	09MAL20B	SD Biosensor	59.4	32.5	8.1	0.0	0.0	NA	NA	NA	NA	NA	99.4	0.6	0.0	0.0	0.0
STANDARD Q Malaria P.f/Pan Ag Test	09MAL30B	SD Biosensor	58.1	33.1	8.8	0.0	0.0	47.5	46.3	6.3	0.0	0.0	NA	NA	NA	NA	NA
VISITECT® Malaria Pf/Pan	0D326	Omega Diagnostics Ltd.	50.0	33.8	16.3	0.0	0.0	38.1	58.8	3.1	0.0	0.0	NA	NA	NA	NA	NA
VISITECT® Malaria Pf/Pv	0D216	Omega Diagnostics Ltd.	53.1	35.0	11.9	0.0	0.0	NA	NA	NA	NA	NA	59.4	40.6	0.0	0.0	0.0

NA, not applicable

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

[a] Denotes no visible band

[b] Calculations include invalid tests

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

Introduction of parasite-based diagnosis into 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 confidence in RDT-based diagnosis lost, which can obviate 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 (*16*). 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 understand other causes of fever in order to devise appropriate management algorithms for parasite-negative cases.

Changing and enforcing regulatory requirements

At national level, regulations 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]

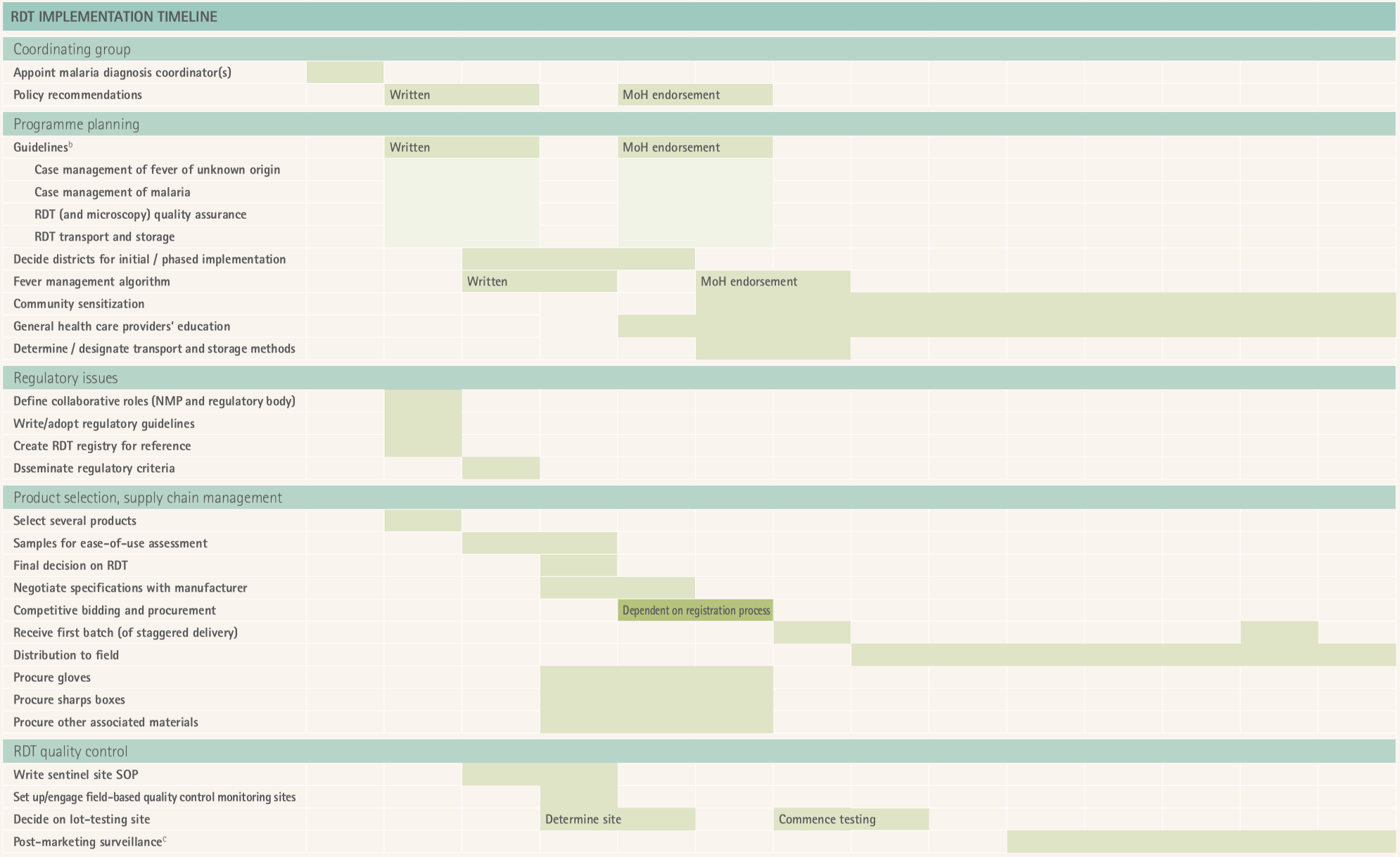
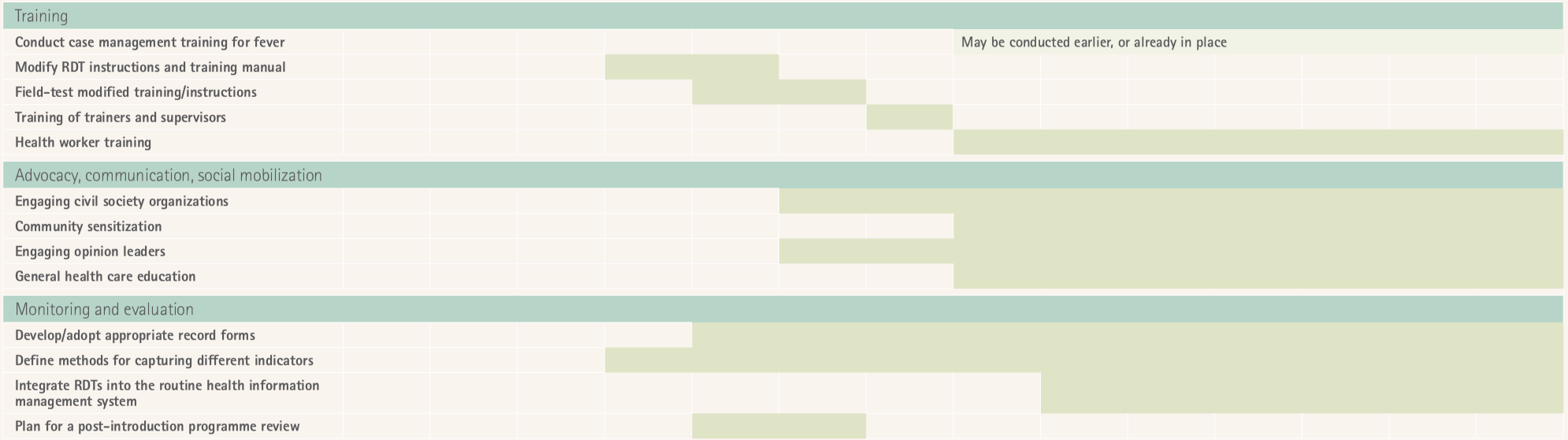


Figure A5.1 *(continued)*



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 (*17*)

[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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