Malaria Rapid Diagnostic Test Performance

Summary results of WHO product testing of malaria RDTs: round 1-8 (2008–2018)

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.

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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

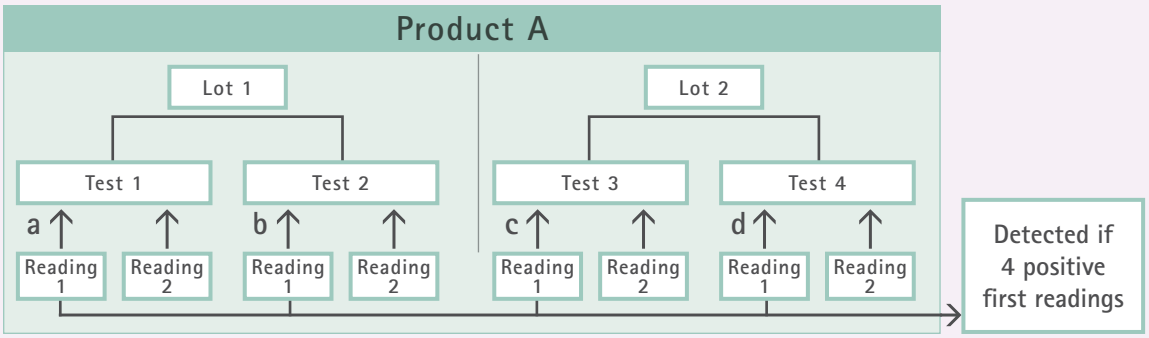
The results (summarized in Figs S1–S3 and Tables S2 and S3) provide comparative data on two lots of products against a panel of parasite samples diluted in blood to a low density (200 parasites/μL) and a higher density (2000 parasites/μL). The former is well below the mean parasite density found in many 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.

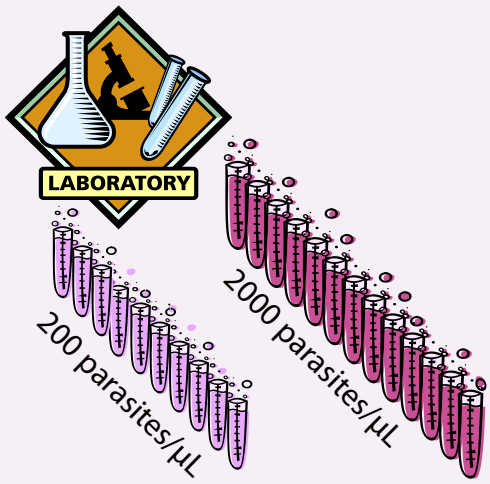
In the above example, the positivity rate is: 9/12 = 75%.

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.

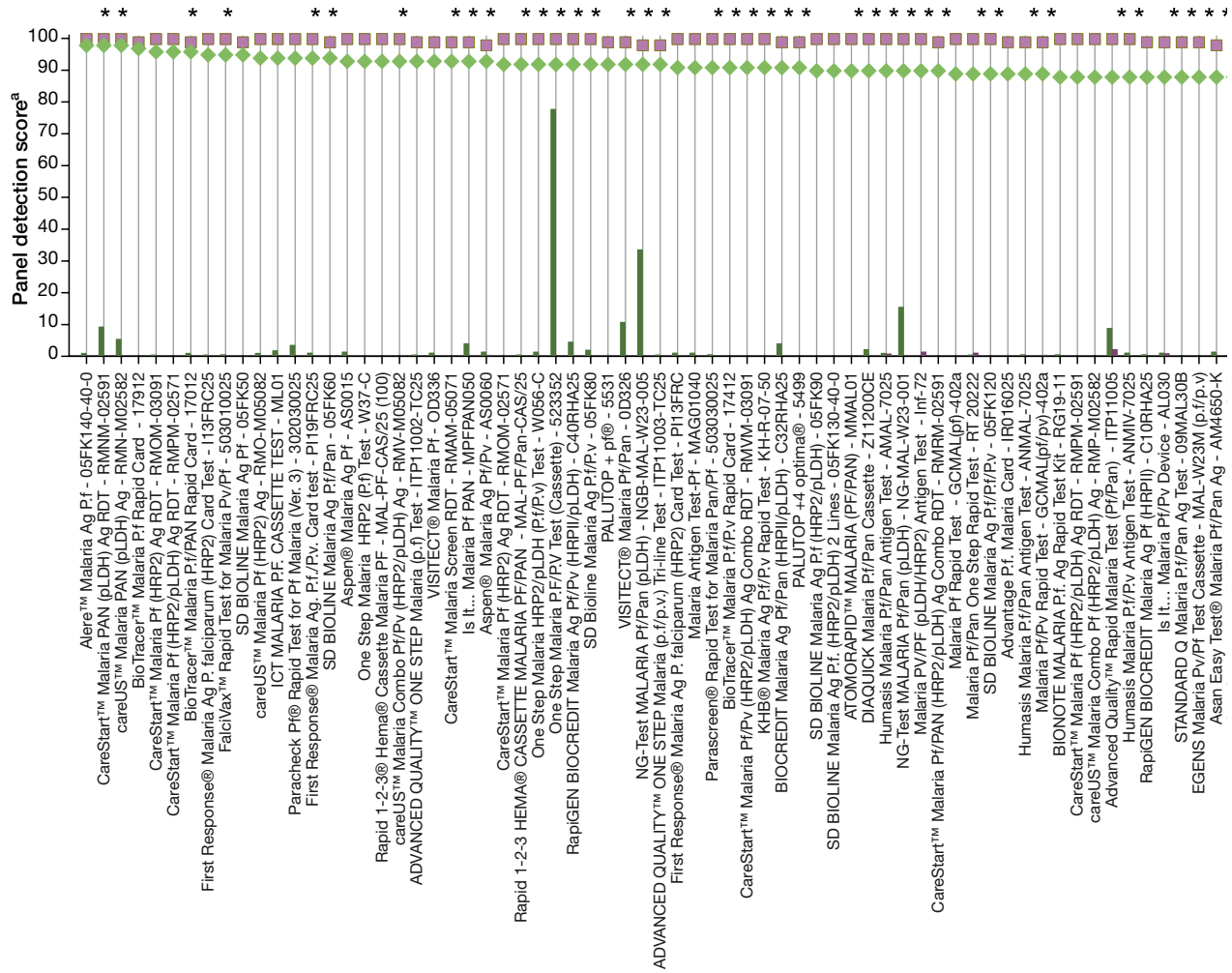
(c) The false positive rate should be less than 10%.

(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.

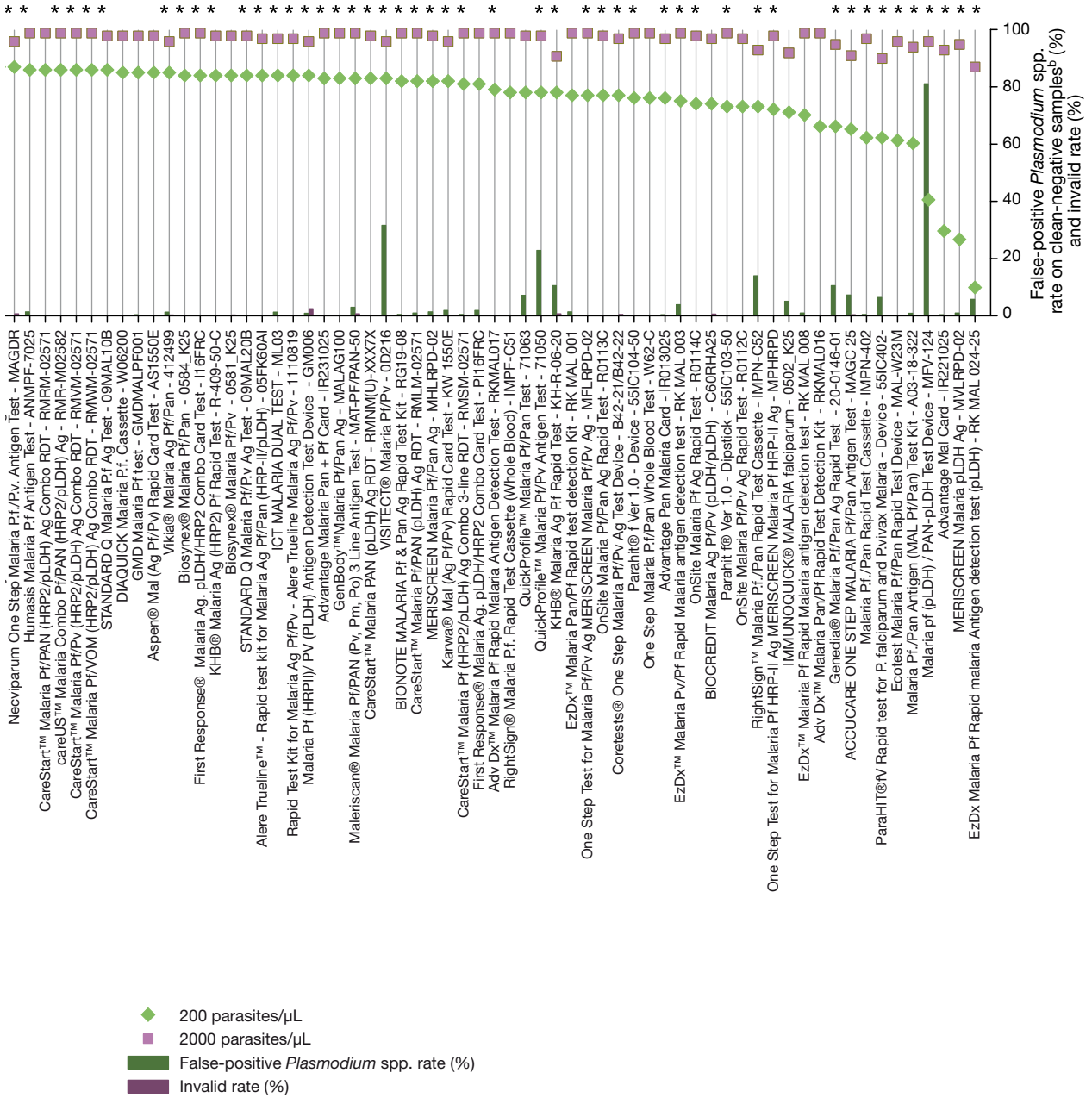
[b] Clean-negative - blood samples from healthy volunteers with no known current illness or blood abnormality.

* 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

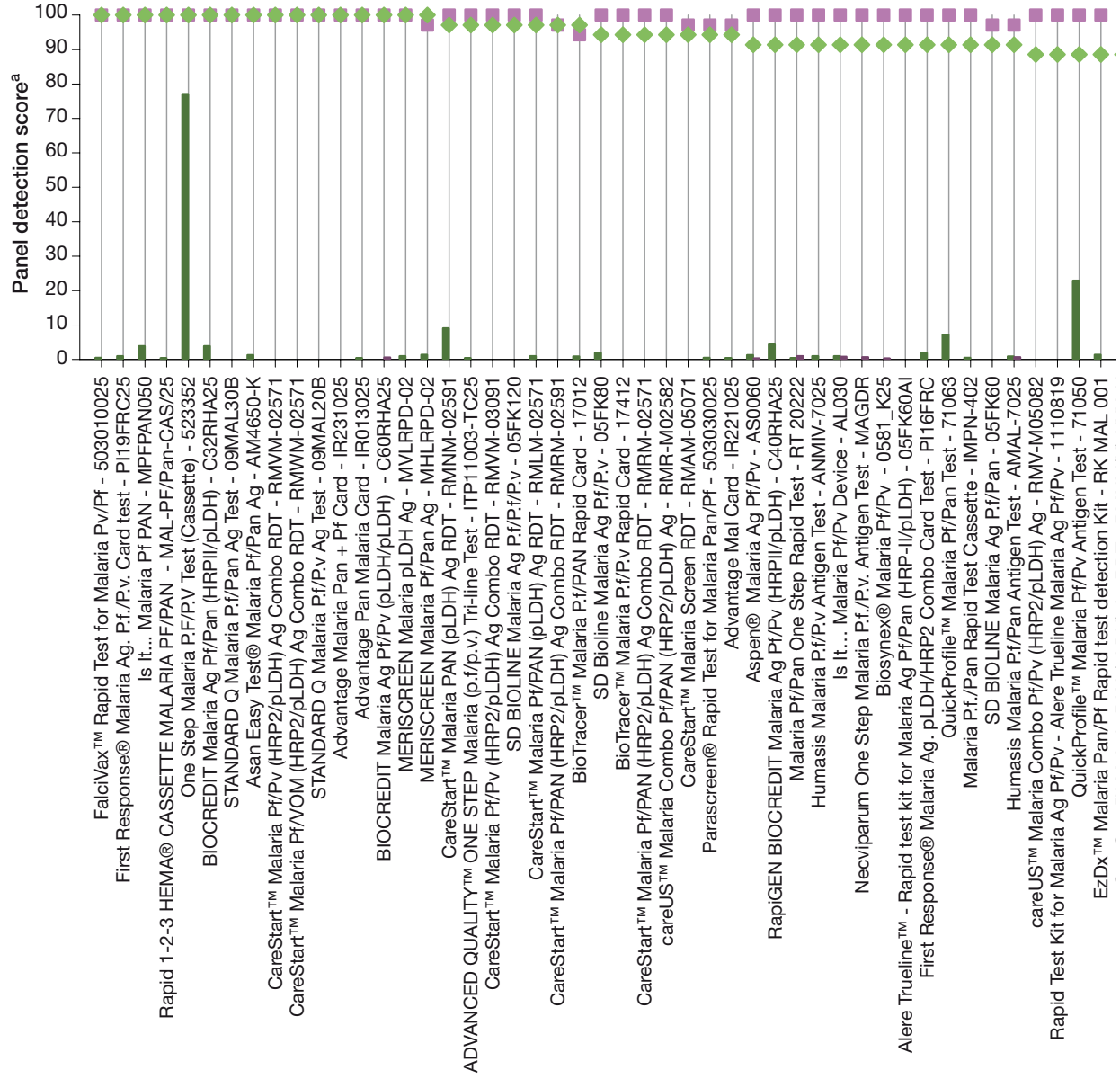
The data are used to set priorities for WHO prequalification dossier review and inspection. As per the new requirements announced in May 2016, manufacturers of products that met the WHO procurement criteria in previous rounds of



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.

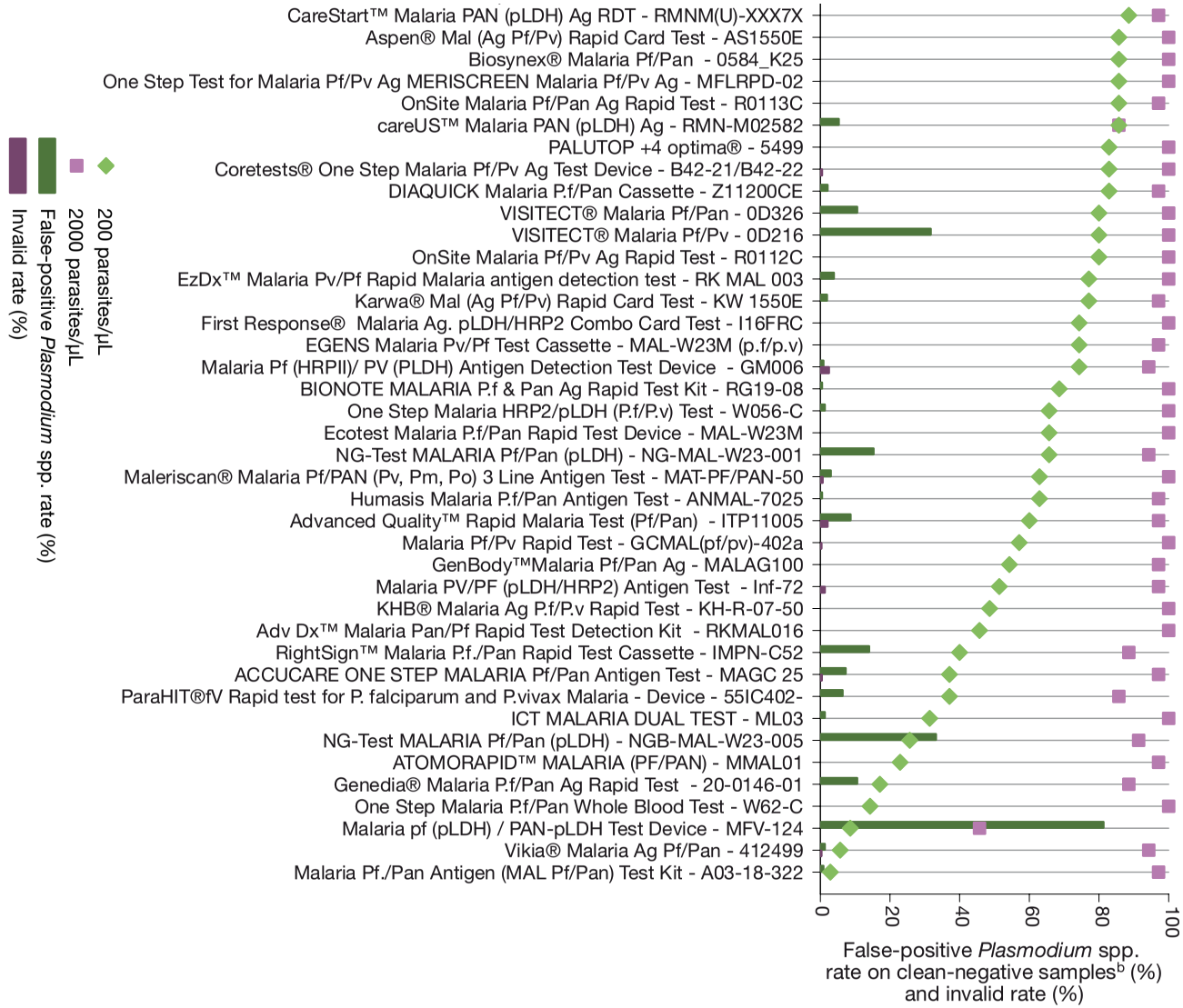
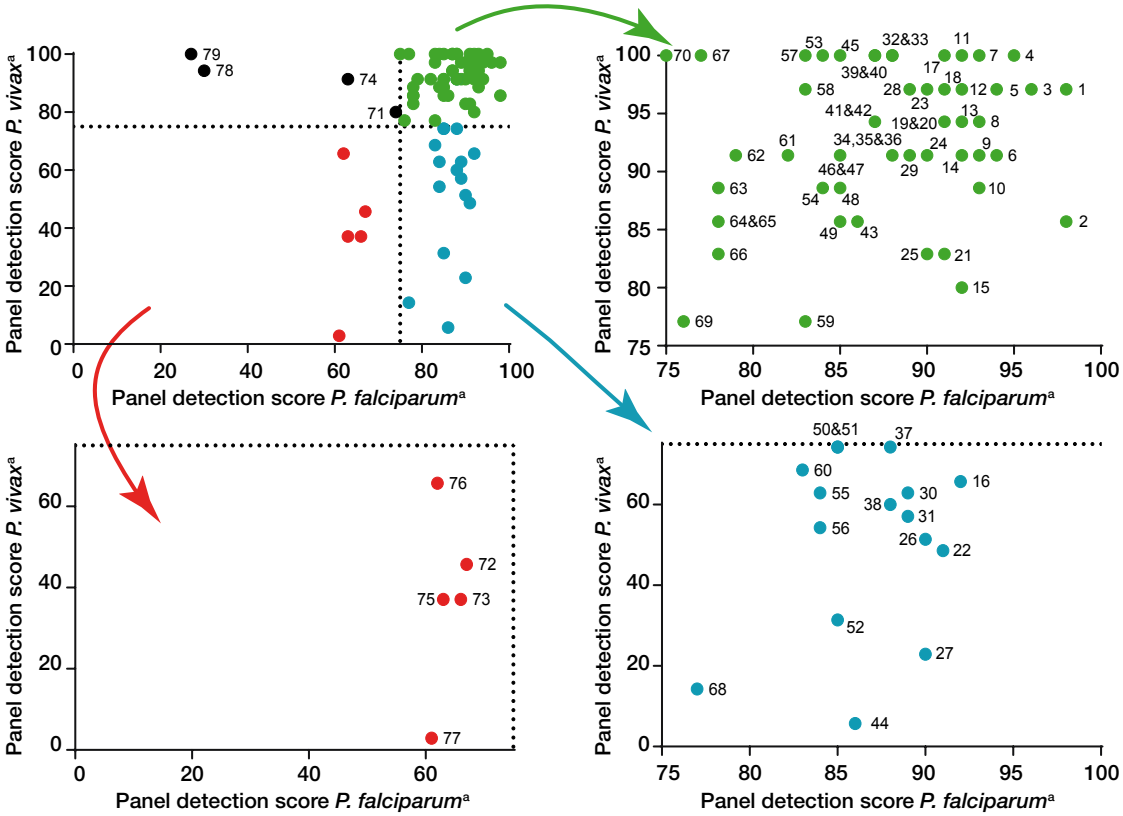

CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
Aspen® Mal (Ag Pf/Pv) Rapid Card Test - AS1550E
Biosynex® Malaria Pf/Pan - 0584_K25
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
careUS™ Malaria PAN (pLDH) Ag - RMN-M02582
PALUTOP +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 Bio, 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	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[o]	I16FRC25	1, 2, 5	
	First Response Malaria Ag *P. falciparum*(HRP2) Card Test	I13FRC25	1	5
	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[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples				
							False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
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	MAL-W23M (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

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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.

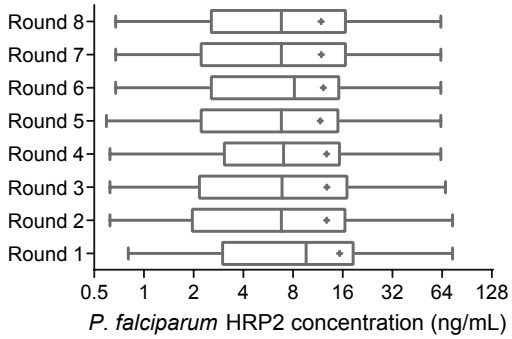


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

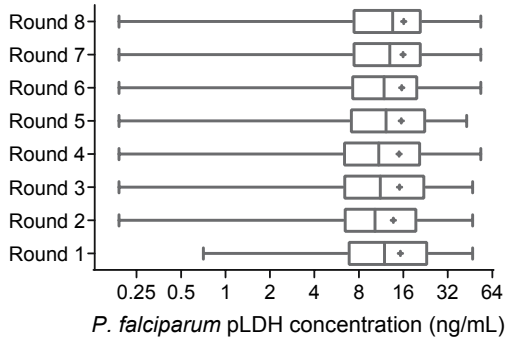


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

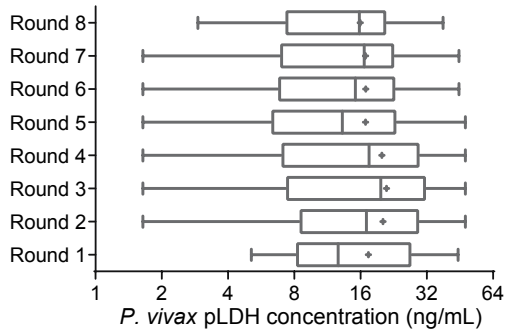


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

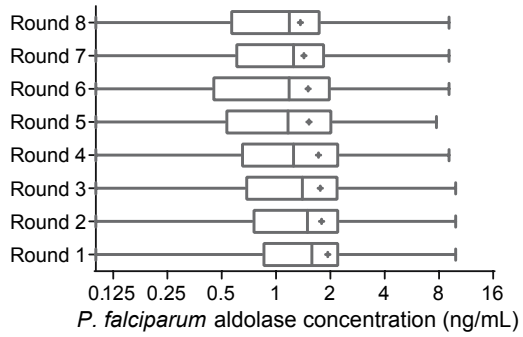


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

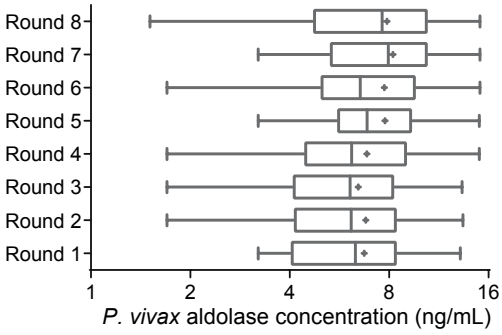


Figure AS1.6: Box-and-whisker plot of distribution of HRP2 (a), pLDH (b) and aldolase (c)concentration (ng/mL) in round 8 *P. falciparum* HRP2-negative panel and round 8 phase-2 panel

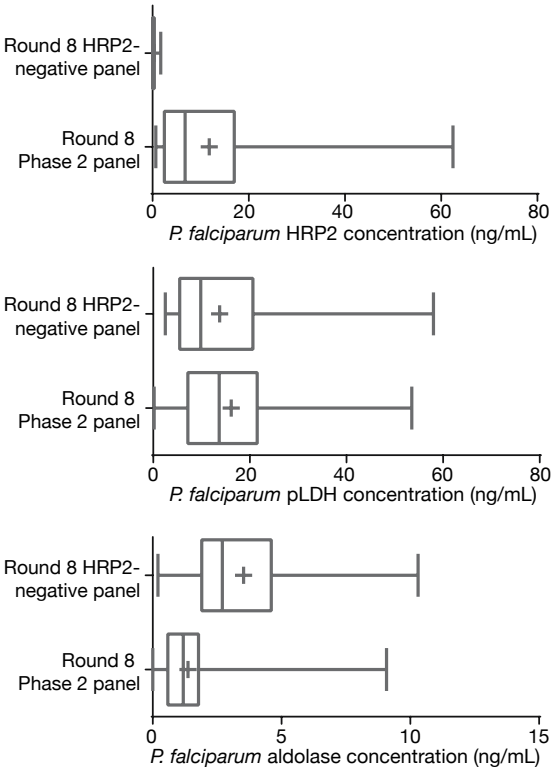


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

	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

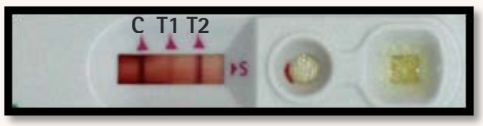
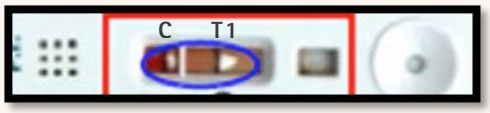
Date of assessment				
Commercial name				
Product code				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed package				
The correctly indicated number of RDTs are in the box				
Desiccant is included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

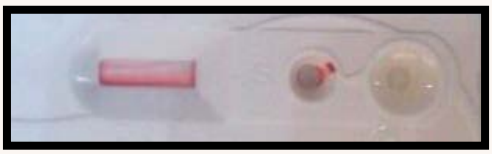
NA, not applicable

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.

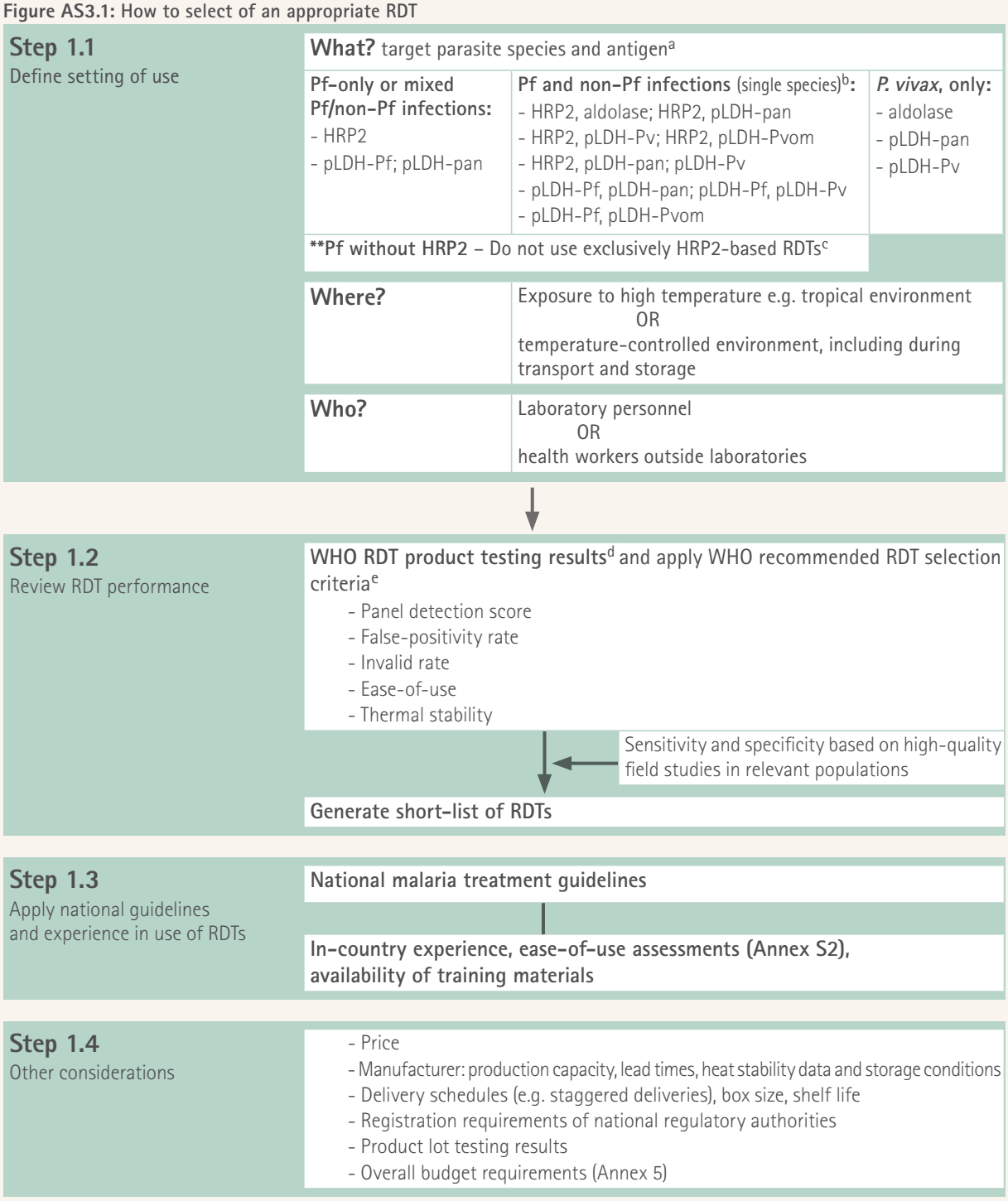
Figure AS2.1: Malaria RDT anomalies encountered in production lots

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)*.

References for annexes

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