Malaria Rapid Diagnostic Test Performance

Summary results of WHO product testing of malaria RDTs: round 1-7 (2008–2016)

World Health Organization

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Because diagnosis matters

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

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

The lists of RDTs included in this report are not exhaustive but reflect those products that were submitted for evaluation in rounds 4–7 of the WHO Malaria RDT Product Testing Programme. Their mention indicates the extent to which these products, as manufactured by the listed companies, were – at the time of their evaluation – found to meet the above-mentioned set of minimum performance criteria. The evaluations indicated in the figures and tables apply only to the specific product listed with its unique product code or catalogue number and as manufactured by the listed company.

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

The fact that certain products are not included in any of the lists and figures in this report indicates that they have not or not yet been submitted for evaluation to the WHO Malaria RDT Product Testing Programme or that their evaluation has not yet been completed and published or that they have been removed from summary reports due to noncompliance with compulsory resubmission requirements. It does not indicate anything in respect of such products' performance. The lists and figures are updated regularly, and malaria RDTs are added to the lists and figures as and when (following voluntary participation in the WHO Malaria RDT Product Testing Programme) their evaluation against the above-mentioned set of minimum performance criteria has been completed.

Although the malaria RDTs listed in the tables and figures are regularly re-evaluated, and updated evaluations are published by WHO, WHO cannot ensure that products on the lists and in figures will continue to meet the performance criteria in the same manner as indicated. WHO recommends therefore that, before procuring a malaria RDT, each lot of that product be tested at one of the two following lot-testing laboratories: the Institut Pasteur du Cambodge, Cambodia, or the Research Institute for Tropical Medicine, Philippines.

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ABBREVIATIONS

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

1. SUMMARY OF PERFORMANCE OF RAPID DIAGNOSTIC TESTS FOR MALARIA: WHO PRODUCT TESTING ROUNDS 1–7

1.1. Introduction

WHO estimates that 3.2 billion people are at risk for malaria. In 2015, there were an estimated 212 million new cases (with an uncertainty range of 148 million to 304 million) and an estimated 429 000 deaths (with an uncertainty range of 235 000 to 639 000). Approximately 90% of these deaths occurred in sub-Saharan Africa and just over 70% were of children under 5 years. Malaria remains endemic in 91 countries and territories and while parasite-based diagnosis is increasing, national surveys between 2013 and 2015 suggest approximately 31% of suspected malaria cases in sub-Saharan Africa were not confirmed with a diagnostic test, resulting in over-use of antimalarial drugs and poor disease monitoring (*1*).

WHO recommends that malaria case management be based on parasite diagnosis in all cases (*2*). The use of antigen-detecting rapid diagnostic tests (RDTs) is a vital part of this strategy, forming the basis for extending access to malaria diagnosis by providing parasite-based diagnosis in areas where good-quality microscopy cannot be maintained. The number of RDTs available and the scale of their use have increased rapidly over the past few years. However, limitations of field trials and the heterogeneous nature of malaria transmission have limited the availability of the good-quality data on performance that national malaria programmes require to make informed decisions on procurement and implementation, and it is difficult to extrapolate the results of field trials to different populations and times. Therefore, in 2006, the WHO Special Programme for Research and Training in Tropical Diseases (TDR) and the Foundation for Innovative New Diagnostics (FIND) launched a programme to systematically evaluate and compare the performance of commercially available malaria RDTs.

The results of WHO's malaria RDT product testing have been published annually since 2009 and form the basis of the procurement criteria of WHO, other United Nations agencies, the Global Fund to Fight AIDS, Tuberculosis and Malaria, national governments and non-governmental organizations. The data have guided procurement decisions, which, in turn, have shifted markets towards better-performing tests (*1*) and are driving overall improvements in the quality of manufacturing.

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

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

This summary presents an overview of the results of rounds 4–7 of malaria RDT product testing and key concepts for understanding and using the results. It is published in conjunction with the release of the full report on round 7. With the exception of products that are no longer manufactured and/or are de-listed because of failure to comply with compulsory resubmission requirements, the results of all rounds of testing should be considered as a single data set. The separate, full reports of each round (*3–8*) should be consulted for further details of methods, product performance and interpretation of the results.

1.2. The WHO product testing programme

The RDT evaluations summarized here were performed in collaboration by WHO, TDR, FIND, the United States Centers for Disease Control and Prevention (CDC) and other partners[1]. All companies that manufacture RDTs according to the ISO 13485:2003 quality system standard were invited to submit

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

products for evaluation. In each round of testing, products were evaluated against geographically diverse, cryopreserved *Plasmodium falciparum* and *P. vivax* clinical samples diluted to 200 and 2000 parasites/µL with consistently comparable concentration ranges of histidine-rich protein II (HRP2), *Plasmodium* lactate dehydrogenase (pLDH) and aldolase determined by quantitative enzyme-linked immunosorbent assay (ELISA) (Annex S1). In the first round of testing, 41 products from 21 manufacturers were evaluated against prepared blood panels of cultured *P. falciparum* parasites, while 29, 50, 48, 42, 41 and 46 products from 13, 23, 27, 34, 22 and 27 manufacturers were evaluated in rounds 2, 3, 4, 5, 6 and 7, respectively. Of these 297 products, 293 progressed to testing against panels of patient-derived *P. falciparum* and *P. vivax* parasites and a parasite-negative panel. Thermal stability was assessed after 2 months of storage at elevated temperature and humidity, and a rudimentary assessment of ease of use was made. In round 6 and 7, specific observations of RDT anomalies were also systematically recorded. Many manufacturers have decided voluntarily to submit products to one or more rounds of testing, and, in round 5, a requirement was instituted to resubmit products for re-evaluation within 5 years of original testing (Table S1). Of the 293 fully evaluated products in rounds 1–7, 31 have been evaluated twice, 21 have been evaluated three times, two evaluated four times and three evaluated five times. Of the 202 unique products tested in the programme, 65 detect *P. falciparum* alone, 143 detect and differentiate *P. falciparum* from non-*P. falciparum* malaria (either pan-specific or species-specific for *P. vivax* or *P. vivax*, *ovale* and *malariae*), 10 detect *P. falciparum* and non-*P. falciparum* malaria without distinguishing between them, and one product was designed to detect *P. vivax* only. Manufacturers submitted two lots of each product for evaluation. When the same products (*9*) were resubmitted in subsequent rounds of testing, the second set of results replaced those from the earlier round. Thus, the performance of some tests in the results below differs from that reported in rounds 1–6.

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

Product testing is part of a continuing programme of work to improve the quality of RDTs in use and to ensure reliable malaria diagnosis in areas where malaria is prevalent. The aim of the evaluation is to provide comparative data on the performance of the submitted production lots of each product. Since 2009, these data have guided procurement decisions by WHO, other United Nations agencies and national governments.

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

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

1.3. Panel detection score and other results of the evaluation

The results (summarized in Figs S1–S3 and Tables S2 and S3) provide comparative data on two lots of products against a panel of parasite samples diluted in blood to a low density (200 parasites/µL) and a higher density (2000 parasites/µL). The former is well below the mean parasite density found in many populations with endemic malaria and is considered close to the threshold that must be detected in order to reliably identify clinical malaria in many settings (*11*). For the purposes of this report, the main measure of performance is the panel detection score (PDS); for each RDT evaluated, the PDS is measured separately at the lower and the higher parasite densities. The summary figures also show the false-positive rates against blood samples containing no malaria parasites or known markers of other diseases and the rate of invalid results.

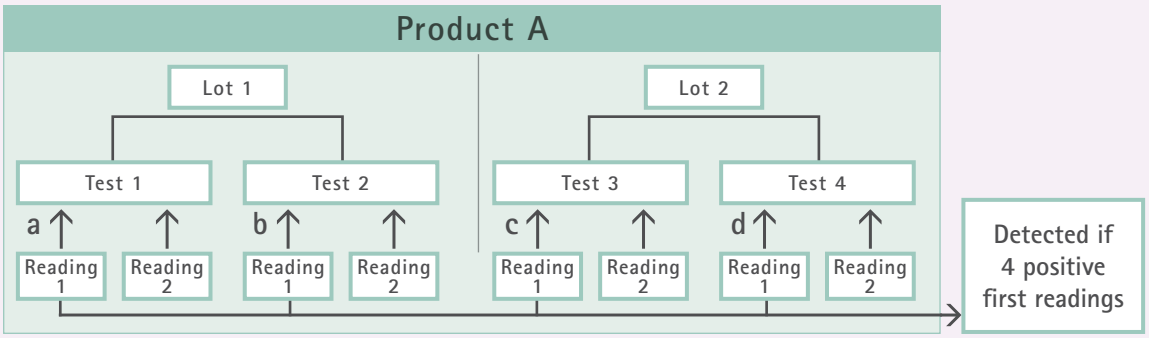
The PDS is the percentage of malaria samples in the panel that give a positive result in two RDTs per lot at the lower parasite density or by a single RDT per lot at the higher parasite density. As each sample is tested with RDTs from two lots, for a sample to be positive at the lower parasite density,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

The PDS for a given RDT is different from the clinical sensitivity of that RDT (also called the true positive rate), which is a measure of the proportion of people known to have the disease who test positive for it. The sensitivity of malaria RDTs is highly dependent on local conditions, including the parasite density in the population; it therefore varies among populations with different levels of transmission, as their level

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

Box 1: Example calculation of panel detection score and positivity rate for product A against a sample density of 200 parasites/µL

The first reading was at the minimum time specified by the manufacturer; the second reading was up to 30 min later[a]. A sample is considered detected only if all first test readings, from both lots, are positive, i.e. readings a, b, c and d must be positive.



[a] second reading results are for internal use only

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

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

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

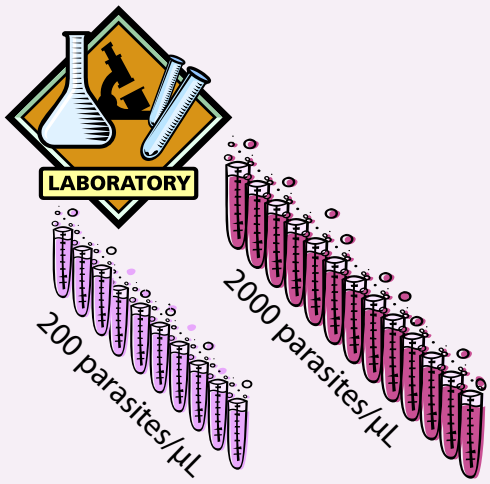
In the above example, the positivity rate is: 9/12 = 75%.

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

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

WHO Malaria RDT Product Testing

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



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

Malaria endemic setting

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

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

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

of immunity affects the parasite density at which they exhibit symptoms that warrant a diagnostic test. Where transmission rates are low, the parasite densities in people with symptoms of malaria are likely to be low, and tests will be less sensitive. Test performance at 200 parasites/µL is therefore particularly important. The results in this report show the comparative performance of RDTs and indicate which products are likely to be more sensitive in the field, particularly in populations with low-density infections.

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

An important caveat to estimating field sensitivity from the PDS provided in this report is that the panels used include only parasites known to express the target antigens. While non-expression of the target antigens has not been recorded for aldolase or pLDH, it is known that parasites that infect people in some areas of South America (Peru, Colombia, Brazil), India and Africa (Eritrea, Ghana, Rwanda) do not express HRP2 (*12–13* , *33-34*). In areas where HRP2-deleted parasites exist, tests for HRP2 will have greatly reduced sensitivity or be incapable of detecting *P. falciparum*. In such populations, only tests for pLDH or aldolase in *P. falciparum* parasites will be effective.

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

Ease-of-use requirements depend on the extent of training and the work environment of the users. Particularly in primary health care settings, the simpler the test, the easier it will be to avoid errors in preparation and interpretation. Certain anomalies resulting from defects in production lots or RDT degradation may affect the running of the test or interpretation and may warrant a field safety notice and corrective action.

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

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

1.4. Summary of outcomes

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

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

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

Although the performance of the products varied widely at low parasite density (200 parasites/µL) in round 7, all products had a high rate of detection of *P. falciparum* at 2000 parasites/µL (PDS of 100%), as did the majority of products for *P. vivax* at 2000 parasites/µL.

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

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

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

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

1.5. De-listing of products in summary report

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

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

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

The results in Table S2 indicate WHO prequalification status and are colour-coded to reflect achievement of WHO performance requirements for RDT procurement. A web-based tool that allows filtering of product testing results by various parameters to assist in selecting products with the performance characteristics most suitable for a country's health programme is available and is maintained by FIND (*15*). This online database has been updated to allow filtering of results by RDT procedural characteristics, such as blood volume requirements, number of buffer drops and time to a result. This will allow identification of products with similar procedures so that, when product replacement is required, another product can be selected with the same or a similar protocol. Use of similar products may reduce the need for user retraining and reduce user error.

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

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

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

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

Box 3: WHO selection criteria for the procurement of RDTs

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

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

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

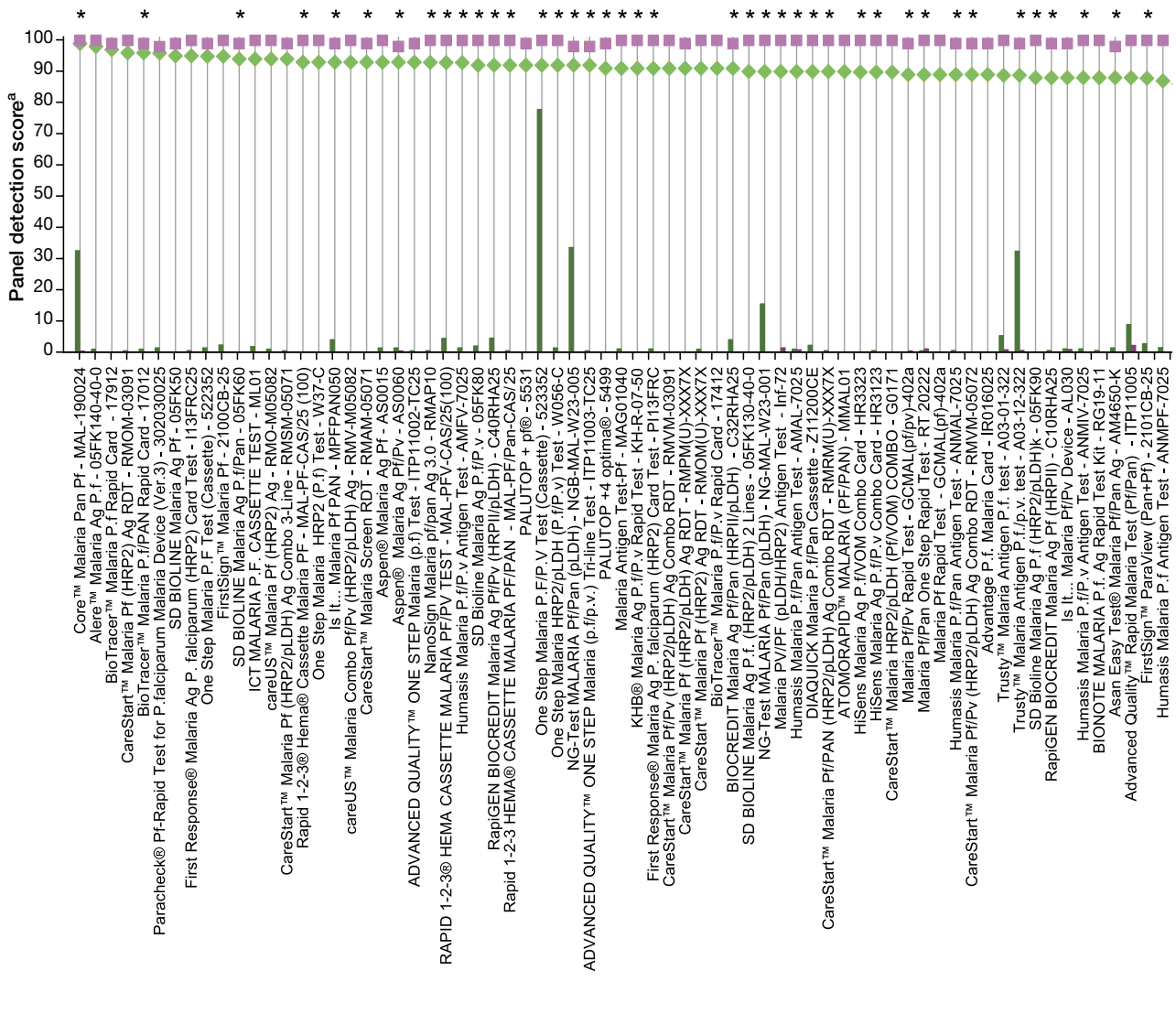
(C) The false positive rate should be less than 10%.

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

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

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

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



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

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

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

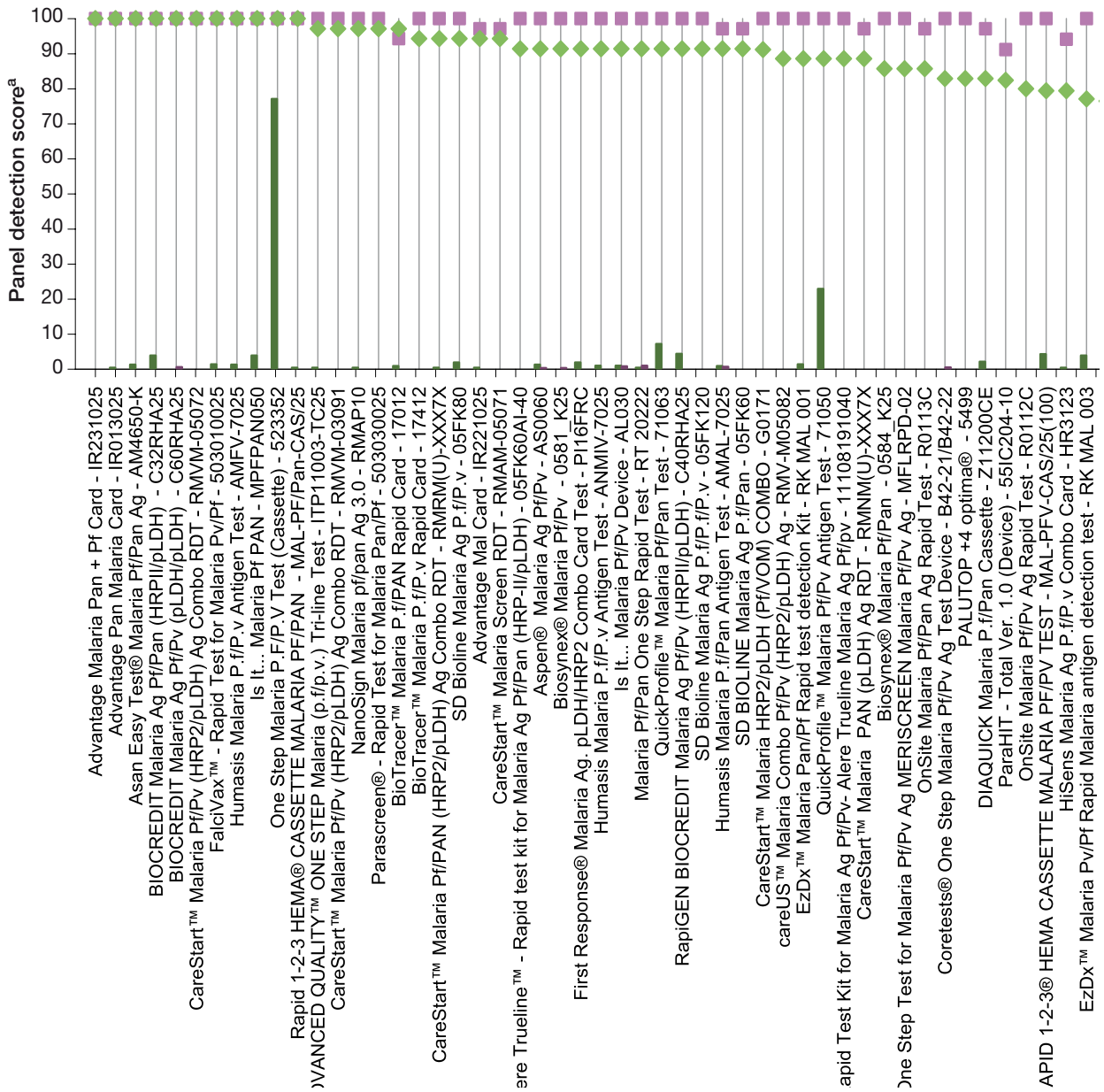
1.7. Product testing and WHO programme for prequalification of diagnostics and medical devices

In the WHO programme for prequalification of diagnostics and medical devices, the results of product testing are used as the laboratory evaluation component of the prequalification process for malaria RDTs. These data are used to set priorities for dossier review and inspection. As of 1 January 2018, WHO prequalification will become a requirement for WHO procurement. Therefore, manufacturers are strongly encouraged to apply.[1] Prequalified RDTs are listed in summary tables and at *http://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/* (accessed 8 March 2017).

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


Vikia® Malaria Ag Pf/Pan - 412499
Malaria Pf/PAN Test - PROMALPFV001
GMD Malaria Pf test - GMDMALPF001
DIAQUICK Malaria P.f. Cassette - W06200
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
SD Bioline Malaria Ag P.f/P.f/P.v - 05FK120
Rapid Test Kit for Malaria Ag Pf/Pv- Alere Trueline Malaria Ag Pf/pv - 11108191040
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
KHB® Malaria Ag (HRP2) Pf Rapid Test - R-409-50-C
ICT MALARIA DUAL TEST - ML03
First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
Biosynex® Malaria Pf/Pv - 0581_K25
Biosynex® Malaria Pf/Pan - 0584_K25
Alere Trueline™ - Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH) - 05FK60AI-40
ParaHIT - Total Ver. 1.0 (Device) - 55IC204-10
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
GenBody™ Malaria Pf/Pan Ag - MALAG100
CareStart™ Malaria PAN (pLDH) Ag RDT - RMNM(U)-XXX7X
Advantage Malaria Pan + Pf Card - IR231025
Maleriscan ® Malaria P.f Antigen Test - MAT-PF-50
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - PI16FRC
FalciVax™ - Rapid Test for Malaria Pv/Pf - 503010025
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test - RKMAL017
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood) - IMPF-C51
QuickProfile™ Malaria Pf/Pv Antigen Test - 71050
QuickProfile™ Malaria Pf/Pan Test - 71063
Parascreen® - Rapid Test for Malaria Pan/Pf - 503030025
KHB® Malaria Ag P.f Rapid Test - KH-R-06-20
OnSite Malaria Pf/Pan Ag Rapid Test - R0113C
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag - MFLRPD-02
EzDx™ Malaria Pan/Pf Rapid test detection Kit - RK MAL 001
Coretests® One Step Malaria Pf/Pv Ag Test Device - B42-21/B42-22
Parahit® f Ver 1.0 - Device - 55IC104-50
One Step Malaria P.f/Pan Whole Blood Test - W62-C
Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
Advantage Pan Malaria Card - IR013025
ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test - RK MAL 003
OnSite Malaria Pf Ag Rapid Test - R0114C
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH) - C60RHA25
RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
Parahit f® Ver 1.0 - Dipstick - 55IC103-50
OnSite Malaria Pf/Pv Ag Rapid Test - R0112C
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag - MPHRPD-01
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
IMMUNOQUICK® MALARIA falciparum - 0502_K25
EzDx™ Malaria Pf Rapid Malaria antigen detection test - RK MAL 008
Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)j - 302040025
MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
ParaHITÂ®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-50
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Devicek - MFV-124F
AZOG hCG Malaria Detection Test Device - MPT-124
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
Malaria Pf/Pv - GM002
Malaria Pf/ PAN - GM004
ABON™ Malaria P.f. Rapid Test Device (Whole Blood) - IMA-402
Advantage Mal Card - IR221025
200 parasites/µl
2000 parasites/µl
False-positive Plasmodium spp. rate (%)
Invalid rate (%)
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)

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



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

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

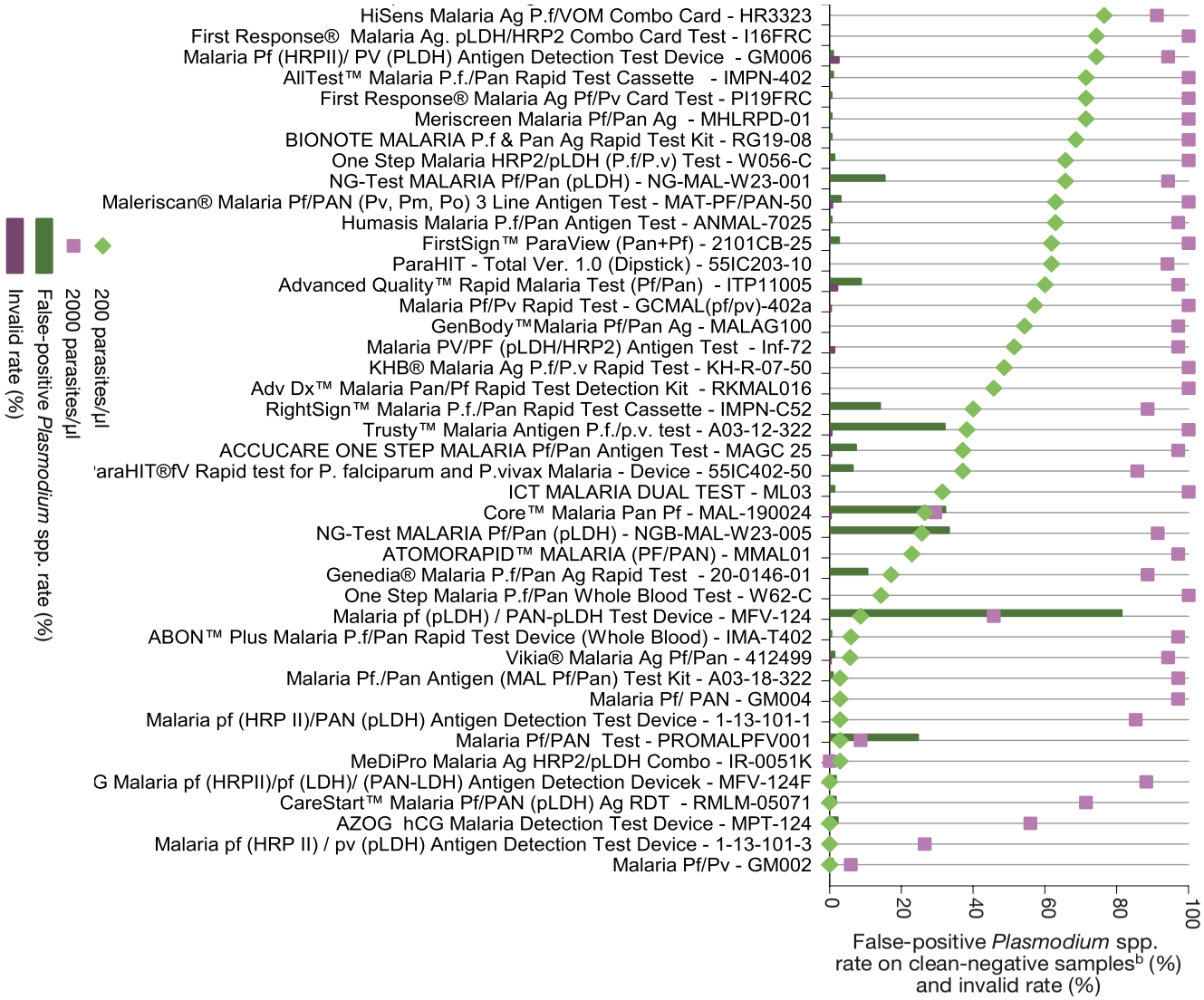
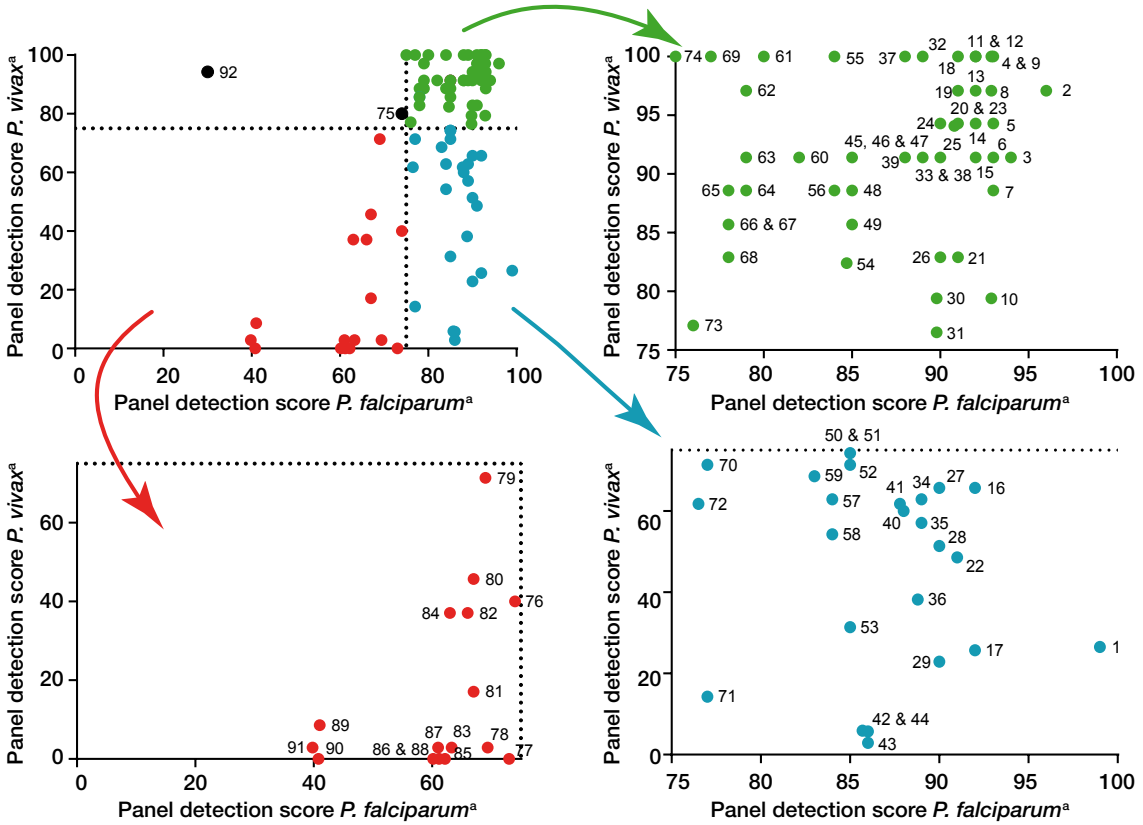

HiSens Malaria Ag P.f/VOM Combo Card - HR3323
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test - I16FRC
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device - GM006
AllTest™ Malaria P.f./Pan Rapid Test Cassette - IMPN-402
First Response® Malaria Ag Pf/Pv Card Test - PI19FRC
Meriscreen Malaria Pf/Pan Ag - MHLRPD-01
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit - RG19-08
One Step Malaria HRP2/pLDH (P.f/P.v) Test - W056-C
NG-Test MALARIA Pf/Pan (pLDH) - NG-MAL-W23-001
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test - MAT-PF/PAN-50
Humasis Malaria P.f/Pan Antigen Test - ANMAL-7025
FirstSign™ ParaView (Pan+Pf) - 2101CB-25
ParaHIT - Total Ver. 1.0 (Dipstick) - 55IC203-10
Advanced Quality™ Rapid Malaria Test (Pf/Pan) - ITP11005
Malaria Pf/Pv Rapid Test - GCMAL(pf/pv)-402a
GenBody™Malaria Pf/Pan Ag - MALAG100
Malaria PV/PF (pLDH/HRP2) Antigen Test - Inf-72
KHB® Malaria Ag P.f/P.v Rapid Test - KH-R-07-50
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit - RKMAL016
RightSign™ Malaria P.f./Pan Rapid Test Cassette - IMPN-C52
Trusty™ Malaria Antigen P.f./p.v. test - A03-12-322
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test - MAGC 25
araHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device - 55IC402-50
ICT MALARIA DUAL TEST - ML03
Core™ Malaria Pan Pf - MAL-190024
NG-Test MALARIA Pf/Pan (pLDH) - NGB-MAL-W23-005
ATOMORAPID™ MALARIA (PF/PAN) - MMAL01
Genedia® Malaria P.f/Pan Ag Rapid Test - 20-0146-01
One Step Malaria P.f/Pan Whole Blood Test - W62-C
Malaria pf (pLDH) / PAN-pLDH Test Device - MFV-124
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood) - IMA-T402
Vikia® Malaria Ag Pf/Pan - 412499
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit - A03-18-322
Malaria Pf/ PAN - GM004
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device - 1-13-101-1
Malaria Pf/PAN Test - PROMALPFV001
MeDiPro Malaria Ag HRP2/pLDH Combo - IR-0051K
G Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Devicek - MFV-124F
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT - RMLM-05071
AZOG hCG Malaria Detection Test Device - MPT-124
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device - 1-13-101-3
Malaria Pf/Pv - GM002
Invalid rate (%)
False-positive Plasmodium spp. rate (%)
2000 parasites/µl
200 parasites/µl
0
20
40
60
80
100
False-positive Plasmodium spp. rate on clean-negative samples[b] (%) and invalid rate (%)

Figure S3: Panel detection score of malaria combination RDTs meeting WHO procurement criteria for false-positive and invalid rates, in phase 2 of rounds 4–7 against wild-type (clinical) samples containing *P. falciparum* and *P. vivax* at low parasite density (200 parasites/µL)



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

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

Table S1: Product resubmissions: WHO malaria RDT product testing rounds 1–7

Manufacturer	Product name	Product code*	Product resubmission Round	
			Voluntary	Compulsory
Access Bio, Inc.	CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-05072[a]	2, 4, 7	
	CareStart™ Malaria HRP2/PLDH (Pf/VOM) COMBO	RMWM(U)-XXX7X[b]	2, 4	
	CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM(U)-XXX7X[c]	1	5
	CareStart™ Malaria HRP2/pLDH (Pf/PAN) Combo	RMRM(U)-XXX7X	1	5
	CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM(U)-XXX7X[e]	1	5
	CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X[f]	2	6
	CareStart™ Malaria Pf/PAN (pLDH) Ag RDT	RMLM-05071[g]	3	7
	CareStart™ Malaria Screen RDT	RMAM-05071[h]	3	7
Advy Chemical Pvt. Ltd. (Affiliate of Bharat Serums & Vaccines Ltd.)	EzDx™ Malaria Pan/Pf Rapid Test Detection Kit	RK MAL 001	4, 5, 6	
ARKRAY Healthcare Pvt. Ltd.[l]	ParaHIT® - f (Device)[j]	551C104-50	3	7
	ParaHIT® - f (Dipstick)[k]	551C103-50	3	7
ASAN Pharmaceutical Co., Ltd	Asan Easy Test® Malaria Pf/Pan Ag	AM4650-K	5, 7	
AZOG	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device[l]	MFV-124R	1, 3	
	Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	3, 5	
Bhat Bio-Tech India (P) Ltd.	Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	4, 5	
Bioland	NanoSign Malaria Pf/Pan Ag	RMAP10	3, 4	
Bionote, Inc.	BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	3, 6	
	BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	3, 6	
Biosynex	IMMUNOQUICK® MALARIA falciparum	0502_K25	1	5
Bio Focus Co., Ltd.	BioTracerTM Malaria P.f/PAN Rapid Card	17012	5, 6, 7	
Blue Cross Bio-Medical (Beijing) Co., Ltd.	One Step Malaria Pf Test (cassette)	522352	2, 3, 4	
	One Step Malaria P.F/P.V Test (Cassette)	523352	4, 5	
CTK Biotech, Inc.	Onsite Pf Ag Rapid Test	R0114C	2, 3, 6	
	Onsite Malaria Pf/Pan Malaria Ag Rapid Test	R0113C	2, 3, 4, 5, 6	
	Onsite Malaria Pf/Pv Ag Rapid Test	R0112C	2, 3, 4, 6	
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024	1, 3	
Guangzhou Wondfo Biotech Co. Ltd.	Wondfo One Step Malaria Pf/Pan Whole Blood Test	W56-C	1, 3	
	One Step Malaria P.f/P.v Whole Blood Test	W056-C	5, 6, 7	
	One Step Malaria P.f Test[m]	W37-C	2, 3, 4, 6, 7	
Humasis Co., Ltd.	Humasis Malaria Pf/Pan Antigen Test	AMAL-7025	4, 5	
ICT INTERNATIONAL	ICT Malaria Combo Cassette Test	ML02	1, 3, 4	
	ICT Malaria Pf Cassette Test	ML01	1, 3	7
	ICT Malaria Dual Test	ML03	3, 5, 7	
InTec Products, Inc.	Advanced Quality™ One Step Malaria Pf Test	ITP11002TC1/TC40	1, 3, 7	5
	Advanced Quality ™One Step Malaria (Pf/Pv) Tri-line Test (whole blood)	ITP11003 TC40	3, 6, 7	
J.Mitra & Co. Pvt. Ltd.	Advantage Pan Malaria Card	IR013025	1	5
	Advantage Mal Card	IR221025	1	5
	Advantage P.f Malaria Card	IR016025	1	5
Lumiquick Diagnostics Inc.	QuickProfileTM Malaria Pf/Pv Antigen Test	71050	6, 7	
Orchid Biomedical Systems	Paracheck® Pf Device - Rapid test for P. falciparum Malaria (Ver. 3)[n]	30301025	1, 3, 4	
	Paracheck® Pf Dipstick - Rapid test for P. falciparum Malaria (Ver.3)[n]	30302025	1, 3, 4	
Premier Medical Corporation Ltd.	First Response® Malaria Ag Combo (pLDH/HRP2)[o]	I16FRC25	1, 2, 5	
	First Response Malaria Ag P. falciparum(HRP2) Card Test	I13FRC25	1	5
RapiGEN Inc.	BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH)	C30RHA25	5, 6, 7	
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf)Cassette WB	KMFC6001	2, 5	
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40	1, 3	
	SD BIOLINE Malaria Ag Pf/Pan	05FK60	1, 3, 5	
	SD BIOLINE Malaria Antigen	05FK50	1	5
	SD Bioline Malaria Ag P.f (HRP2/pLDH)	05FK90	3, 6	
	SD Bioline Malaria Ag P.f/P.v	05FK80	2	6
Unimed International Inc.	FirstSign™ - ParaView (Pan+Pf) Malaria Test	2101 CB-25	2, 4	
Vision Biotech (Pty) Ltd / Orgenics (Alere Healthcare (Pty) Ltd subsidaries)	Malaria Rapid Combo/Clearview® Malaria Combo	VB11[p]	1, 3	
	Malaria Rapid Pf /Clearview ®Malaria Pf	VB01	1, 3, 5	
	Malaria Rapid Dual/Clearview® Malaria Dual Test Device	VB20[p]	1, 3, 5	
Zephyr Biomedical Systems	Malascan™ Device - Rapid test for Malaria Pf/Pan	50402025	1, 3	
	Parabank™ Device - Rapid test for Malaria Pan	50301025	1, 3	
	Parascreen™ Device -Rapid test for Malaria Pan/Pf	50310025; 503030025 (rd 6)	1, 3, 4, 5, 6	
	Falcivax Rapid Test for Malaria Pv/Pf (device)	50300025; 503010025 (rd 6)	2, 4, 6	

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

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

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

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

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

[e] Previously listed with product code G0111

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

[g] Previously listed with product code G0121

[h] Previously listed with product code G0231

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

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

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

[l] Round 1 product name error : published - Malaria Pf (HRPII)/pv-LDH) Antigen Detection Test Device Code ; corrected product name: Malaria Pf (HRPII/PAN-LDH) Antigen Detection Test Device Code. No change in product code.

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

[n] Ver.3 was introduced after round 1

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

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

Table S2: Malaria RDT phase 2 performance in rounds 4–7 against wild type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) and high (2000) parasite density (parasites/µl) and clean-negative samples

Product	Product code	Manufacturer	Panel detection score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean negative samples			
							Pf samples	Pv samples	Pf samples	Pv samples				
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
Pf only														
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	32.7	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	4	No
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	80.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test[j]	ITP11002-TC25	InTec Products, Inc.	93.0	NA	99.0	NA	NA	0.0	NA	0.0	0.4	0.0	7	Yes
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	89.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	5	Yes
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	98.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9 (231)	0.1	7	Yes
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	93.0	NA	100.0	NA	NA	0.7	NA	0.0	1.3	0.0	7	Yes
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	88.0	NA	100.0	NA	NA	0.0	NA	0.0	0.5	0.0	6	Yes
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	97.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
CareStart™ Malaria HRP2 (Pf)	RMOM(U)-XXX7X	Access Bio, Inc.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	5	Yes[m]
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	96.0	NA	100.0	NA	NA	0.0	NA	0.0	0.4	0.0	7	Yes
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X	Access Bio, Inc.	91.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line[k]	RMSM-05071	Access Bio, Inc.	94.0 (94/38)	NA	99.0 (99/92)	NA	NA	2.1	NA	1.4	0.4	0.0	7	Yes
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	94.0	NA	100.0	NA	NA	0.0	NA	0.0	0.9	0.0	7	Yes
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	86.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	71.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.1	6	No
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	95.0	NA	100.0	NA	NA	0.7	NA	0.0	0.4	0.0	5	Yes[m]
First Response® Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	91.0	NA	100.0	NA	NA	0.0	NA	0.0	1.0	0.0	6	Yes
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	94.9	NA	100.0	NA	NA	0.7	NA	1.5	2.2 (231)	0.2	4	Yes
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	87.0	NA	100.0	NA	NA	1.4	NA	1.4	1.4	0.0	6	Yes
ICT MALARIA P.F. CASSETTE TEST[j]	ML01	ICT INTERNATIONAL	94.0	NA	100.0	NA	NA	5.0	NA	1.4	1.7	0.0	7	Yes
IMMUNOQUICK® MALARIA falciparum	0502_K25	Biosynex	72.0	NA	93.0	NA	NA	3.6	NA	4.3	5.1 (234)	0.2	5	No
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co.,Ltd.	85.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	79.0	NA	91.8 (98)	NA	NA	11.4	NA	12.9	10.6 (235)	0.7	5	No
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	91.0	NA	100.0	NA	NA	1.4	NA	1.4	1.0	0.0	6	Yes
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	NA	100.0	NA	NA	0.0 (139)	NA	0.0	0.0	0.1	7	Yes
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	83.7	NA	98.0	NA	NA	1.5	NA	0.0	0.4	0.2	4	Yes
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	86.0	NA	99.0	NA	NA	2.9	NA	1.4	0.4 (231)	0.1	7	Yes
One Step Malaria HRP2 (P.f) Test[j]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	93.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	94.9	NA	99.0	NA	NA	0	NA	1.5	1.3	0.0	4	Yes
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	73.0	NA	99.0	NA	NA	0.7	NA	0.0	0.0	0.0	7	No
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	75.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.2	6	Yes
PALUTOP + pf®	5531	ALLDIAG SA	92.0	NA	99.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes
Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver.3)	302030025	Orchid Biomedical Systems	95.9	NA	98.0	NA	NA	0.0	NA	0.0	1.3	0.0	4	Yes
Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)[j]	302040025	Orchid Biomedical Systems	70.4	NA	99.0	NA	NA	0.0	NA	0.0	0.9	0.0	4	No
Parahit f® Ver 1.0 - Dipstick[j]	55IC103-50	ARKRAY Healthcare Pvt Ltd[n]	74.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	No
Parahit® f Ver 1.0 - Device[j]	55IC104-50	ARKRAY Healthcare Pvt Ltd[n]	77.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	7	Yes[m]
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	93.0	NA	100.0	NA	NA	2.9 (139)	NA	0.0	0.0	0.2	6	Yes
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	88.0	NA	99.0	NA	NA	0.7	NA	0.0	0.5 (207)	0.2	6	Yes
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	79.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0	0.0	6	Yes

Table S2 *(continued)*

Product	Product code	Manufacturer	Panel detection score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean negative samples			
							Pf samples	Pv samples	Pf samples	Pv samples				
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
SD Bioline Malaria Ag P.f (HRP2/pLDH)[k]	05FK90	Standard Diagnostics, Inc.	88.0 (87/52)	NA	100.0 (100/97)	NA	NA	0.7	NA	0.0	0.0	0.0	6	Yes[m]
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	90.0	NA	100.0	NA	NA	0.0	NA	0.0	0.0 (231)	0.1	7	Yes
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	95.0	NA	99.0	NA	NA	0.0	NA	2.9	0.0	0.0	5	Yes[m]
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	88.8	NA	100.0	NA	NA	4.4 (135)	NA	2.9	5.2 (230)	0.7	4	Yes
Pf and Pan														
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	85.7	5.9	100.0	97.1	0.0	0.0	0.0	0.0	0.4	0.0	4	No
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	66.0	37.1	92.0	97.1	0.3	0.0 (139)	0.0 (199)	0.0	7.3 (234)	0.4	5	No
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	67.0	45.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	No
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	88.0	60.0	100.0	97.1	0.3 (389)	6.7 (134)	0.0 (197)	1.4	8.7 (231)	2.1	5	No
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	30.0	94.3	94.0	97.1	1.5	0.7	0.5	0.0	0.4	0.0	5	No
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	84.0	100.0	100.0	100.0	3.5	0.0	0.0	0.0 (69)	0.0	0.2	5	Yes
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	85.0	91.4	98.0	100.0	1.3	0.0	1.0	0.0	0.0	0.0	7	Yes
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	69.0	71.4	96.0	100.0	1.3	0.0	2.0	0.0	0.9	0.0	7	No
Asan Easy Test® Malaria Pf/Pan Ag [j]	AM4650-K	ASAN Pharmaceutical Co., Ltd	88.0	100.0	98.0	100.0	0.5 (399)	0.0	1.0	0.0	1.3	0.1	7	Yes
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	93.0	91.4	98.0	100.0	0.3 (399)	1.4 (138)	1.0	0.0	1.3 (231)	0.3	7	Yes
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	90.0	22.9	100.0	97.1	0.0 (399)	2.9	0.0	0.0	0.0 (207)	0.2	6	No
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device[k]	MFV-124F	AZOG, INC.	62.2 (62/3.1)	0.0	98.0 (98/37.8)	88.2	0.0 (390)	5.2	0.0	0.0	1.7 (231)	0.3	4	No
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) [j]	C32RHA25	RapiGEN Inc.	91.0	100.0	99.0	100.0	0.0	0.0	0.5	0.0	3.9	0.0	7	Yes
BIONOTE MALARIA P.f & Pan Ag Rapid Test Kit	RG19-08	BioNote, Inc.	83.0	68.6	100.0	100.0	0.0	0.0	0.0	0.0	0.5	0.0	6	No
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	85.0	85.7	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
BioTracer™ Malaria P.f/PAN Rapid Card [j]	17012	Bio Focus Co., Ltd.	96.0	97.1	99.0	94.3	0.8	0.7	0.5	2.9	0.9	0.0	7	Yes
CareStart™ MALARIA Pf/PAN (pLDH) Ag RDT [j]	RMLM-05071	Access Bio, Inc.	73.0	0.0	100.0	71.4	0.0	0.7	0.0	0.0	1.7	0.0	7	No
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag COMBO RDT	RMRM(U)-XXX7X	Access Bio, Inc.	90.0	94.3	100.0	100.0	1.5	0.7	0.0	0.0	0.4	0.0	5	Yes[m]
CareStart™ Malaria Screen RDT [j]	RMAM-05071	Access Bio, Inc.	93.0	94.3	99.0	97.1	1.3	0.0	0.5	0.0	0.0 (231)	0.1	7	Yes
Core™ Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	99.0	26.5	100.0	29.4	0.0	33.8	0.0	42.7	32.2 (230)	0.3	4	No
DIAQUICK Malaria P.f/Pan Cassette	Z11200CE	DIALAB GmbH	90.0	82.9	100.0	97.1	0.3	2.9	0.0	1.5 (67)	2.1	0.2	5	Yes
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	78.0	88.6	100.0	100.0	0.3	0.0	0.0	0.0	1.4	0.0	6	Yes
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation Ltd.	85.0	74.3	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0	5	No
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	82.0	91.4	100.0	100.0	1.5	0.0	0.0	0.0	1.9 (207)	0.1	6	Yes
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	87.8	61.8	100.0	100.0	0.3	1.5	0.0	0.0	2.6	0.0	4	No
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	84.0	54.3	100.0	97.1	0.0	0.0	0.0	0.0	0.0 (235)	0.2	5	No
Genedia® Malaria P.f/Pan Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	67.0	17.1	96.0	88.6	0.0	13.6	0.0	7.1	10.6	0.1	5	No
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	90.0	91.4	100.0	97.1	0.5 (396)	0.0 (138)	0.0 (199)	1.4	0.9 (235)	0.7	5	Yes
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis Co., Ltd.	89.0	62.9	99.0	97.1	0.0	0.7 (139)	0.0	1.4	0.5	0.1	6	No
ICT MALARIA DUAL TEST [j]	ML03	ICT INTERNATIONAL	85.0	31.4	98.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0	7	No
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	93.0	100.0	99.0	100.0	2.0	0.0	0.5	0.0	3.9	0.0	7	Yes
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	88.0	91.4	99.0	100.0	0.5 (395)	0.0	0.0	0 (68)	1.0 (206)	0.8	6	Yes
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	63.3	2.9	100.0	85.3	0.0	0.0 (135)	0.0	0.0	0.0	0.1	4	No
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	41.0	8.6	97.0	45.7	22.5	47.9	1.5	35.7	81.3 (235)	0.1	5	No
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	61.0	2.9	95.0	97.1	0.0 (3.98)	4.3	0.0 (199)	0.0	0.9	0.2	5	No
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	39.8	2.9	94.9	97.1	0.3	0.7	0.0	0.0	0.0	0.0	4	No

(continued)

Table S2: Malaria RDT phase 2 performance in rounds 4–7 against wild type (clinical) samples containing *P. falciparum* and *P. vivax* at low (200) and high (2000) parasite density (parasites/µl) and clean-negative samples *(continued)*

Product	Product code	Manufacturer	Panel detection score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean negative samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples	Pv samples	Pf samples	Pv samples				
							False positive non-Pf infection[e]	False positive Pf infection[f]	False positive non-Pf infection[g]	False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	91.4	100.0	100.0	0.0 (398)	0.7 (138)	0.0 (199)	0.0 (69)	0.4 (232)	1.0	5	Yes
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	69.4	2.9	99.0	0.0	0.0 (391)	0.0	0.0	1.5	0.9	0.1	4	No
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	77.0	71.4	100.0	100.0	1.3	0.0	0.0	0.0	0.5	0.0	6	No
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	92.9	97.1	100.0	100.0	0.8	0.0	0.0	0.0	0.4	0.0	4	Yes
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	90.0	65.7	100.0	94.3	0.5 (399)	9.3	0.0	4.3	15.3	0.1	5	No
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	92.0	25.7	98.0	91.4	0.8 (399)	3.6 (139)	1.0	4.3	33.2	0.2	7	No
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	77.0	14.3	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	6	No
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	78.0	85.7	99.0	97.1	0.0 (398)	0.0	0.5	1.4	0.0 (207)	0.2	6	Yes
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	ARKRAY Healthcare Pvt. Ltd.[n]	84.7	82.4	99.0	91.2	0.3	0.0	0.5	3.0 (67)	0.0	0.1	4	Yes
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	ARKRAY Healthcare Pvt. Ltd.[n]	76.5	61.8	100.0	94.1	0.8	0.0	0.0	1.5	0.0	0.0	4	No
Parascreen® - Rapid Test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	79.0	97.1	100.0	100.0	2.3	0.0	0.0	0.0	0.0	0.0	6	Yes
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	79.0	91.4	99.0	100.0	6.5	1.4	0.5 (199)	0.0	7.2	0.1	6	Yes
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-PF/Pan-CAS/25	Hema Diagnostic Systems	92.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.4	0.0	7	Yes
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	74.0	40.0	94.0	88.6	2.0	2.9	0.5	5.7	14.0	0.0	5	No
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	94.0	91.4	99.0	97.1	0.8	0.7	0.5	1.4	0.0	0.0	5	Yes[m]
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	86.0	5.7	97.0	94.3	0.0	0.7 (139)	0.5 (199)	0.0 (69)	1.3 (235)	0.3	5	No
Pf and Pv/Pvom														
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test[j]	ITP11003-TC25	InTec Products, Inc.	92.0	97.1	98.0	100.0	1.0	0.0	1.0	1.4 (69)	0.4	0.1	7	Yes
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	75.0	100.0	98.0	100.0	1.0 (399)	0.0 (139)	1.0 (199)	1.5 (68)	0.0 (230)	0.6	7	Yes
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	85.0	91.4	99.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0 (229)	0.3	7	Yes
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	91.0	94.3	100.0	100.0	0.0	0.0	0.0	0.0 (69)	0.0	0.1	6	Yes
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	91.0	97.1	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT[j]	RMVM-05072	Access Bio, Inc.	89.0	100.0	99.0	100.0	1.8	0.0	2.0	0.0	0.0 (231)	0.1	7	Yes[m]
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	93.0	88.6	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	78.0	82.9	98.0	100.0	2.8 (399)	0.0 (138)	1.0	0.0	0.0 (207)	0.5	6	Yes
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	76.0	77.1	100.0	100.0	1.3	1.4	0.0	1.4	3.9	0.0	6	Yes
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	80.0	100.0	99.0	100.0	0.5	0.0	0.5	0.0	1.4	0.0	6	Yes
First Response® Malaria Ag *Pf/Pv* Card Test	PI19FRC	Premier Medical Corporation Ltd.	85.0	71.4	100.0	100.0	0.0	0.0	0.0 (199)	0.0	0.5 (207)	0.2	6	No
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	89.8	79.4	100.0	94.1	0.3 (391)	0.0	0.5	0.0	0.4	0.1	4	Yes
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	89.8	76.5	100.0	91.2	0.0	0.0	0.5	0.0	0.0	0.0	4	Yes
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	92.9	100.0	100.0	100.0	0.5	0.7	0.5	1.5	1.3	0.0	4	Yes
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis Co., Ltd.	88.0	91.4	100.0	100.0	0.3	0.7	0.0	0.0	1.0 (207)	0.1	6	Yes
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	91.0	48.6	100.0	100.0	0.3	0.0	0.0	0.0	0.0	0.0	6	No
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	60.2	0.0	92.9	26.5	0.5	0.0 (135)	3.1 (195)	1.5	0.0 (230)	0.5	4	No
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	85.0	74.3	97.0	94.3	1.5 (391)	6.5 (138)	3.6 (195)	2.9	0.9 (232)	2.5	5	No
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.8	0.0	94.9	5.9	0.8	0.7	0.5	0.0	0.9	0.0	4	No
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	89.0	57.1	99.0	100.0	0.0	0.0	0.5 (199)	0.0	0.0 (231)	0.3	7	No
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	90.0	51.4	100.0	97.1	0.0 (395)	0.0 (137)	0.5 (198)	0.0	0.0 (203)	1.3	6	No
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	84.0	62.9	100.0	100.0	27.3 (399)	5.8 (139)	87.4 (199)	4.3 (69)	3.0 (232)	0.7	5	No

Table S2 *(continued)*

Product	Product code	Manufacturer	Panel detection score[a]				False positive rates (%)				Total false positive rates[b] (%)	Invalid rate (%)[l]	Round	Meets WHO procurement criteria
			200 parasites/µl		2000 or 5000 parasites/µl		200 parasites/µl		2000 parasites/µl		Clean negative samples			
			Pf samples[c]	Pv samples[d]	Pf samples[c]	Pv samples[d]	Pf samples: False positive non-Pf infection[e]	Pv samples: False positive Pf infection[f]	Pf samples: False positive non-Pf infection[g]	Pv samples: False positive Pf infection[h]	False positive *Plasmodium* spp. Infection[i]			
One Step Malaria HRP2/pLDH (P.f/P.v) Test [j]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	92.0	65.7	100.0	100.0	0.3	0.0	1.0	0.0	1.3	0.0	7	No
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	92.0	100.0	100.0	100.0	21.5	53.6	9.0	34.3	77.1	0.0	5	No
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	78.0	85.7	100.0	100.0	0.5	0.7	0.0	1.4	0.0	0.0	7	Yes
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	74.0	80.0	98.0	100.0	0.0 (399)	1.4	0.0	0.0	0.0 (207)	0.2	6	No
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device	55IC402-50	ARKRAY Healthcare Pvt. Ltd.[n]	63.0	37.1	91.0	85.7	2.0 (399)	5.7	0.5	2.9	6.4	0.1	5	No
QuickProfile™ Malaria Pf/Pv Antigen Test [j]	71050	Lumiquick Diagnostics Inc.	79.0	88.6	99.0	100.0	39.8	0.0	27.5	0.0	22.9 (231)	0.1	7	No
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	92.9	79.4	100.0	100.0	0.0	0.7	0.0	1.5	4.3	0.0	4	Yes
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	92.0	91.4	100.0	100.0	2.5 (399)	0.0	1.0	2.9	4.4 (207)	0.2	6	Yes
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	92.0	94.3	100.0	100.0	0.5	0.7	0.0	0.0	1.9	0.0	6	Yes[m]
Rapid Test Kit for Malaria Ag Pf/Pv - Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	85.0	88.6	98.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	7	Yes
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	88.8	38.2	99.0	100.0	13.3	27.4 (135)	16.0 (194)	19.4 (67)	32.0 (231)	0.5	4	No
Pf, Pf and Pv														
SD Bioline Malaria Ag P.f/P.f/P.v [k]	05FK120	Standard Diagnostics, Inc.	85.0 (84/36)	91.4	100.0 (100/98)	100.0	0.0	0.0	0.5	0.0	0.0	0.0	6	Yes
Pf, Pv and Pan														
PALUTOP +4 optima®	5499	ALLDIAG SA	91.0	82.9[p]	99.0	100.0[p]	1.3	0.7	0.5	0.0	0.0	0.0	7	Yes
Pan only														
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	77.0	100.0	98.0	100.0	NA	NA	NA	NA	0.4	0.0	5	Yes
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	61.2	0.0	99.0	55.9	NA	NA	NA	NA	2.2	0.2	4	No
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM(U)-XXX7X	Access Bio, Inc.	84.0	88.6	99.0	97.1	NA	NA	NA	NA	0.0	0.0	5	Yes[m]

NA, not applicable

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

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

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

[c] Round 1, n=79; Round 2, n=100; Round 3, n=99; Round 4, n=98; Round 5, n=100; Round 6, n=100; Round 7, n=100

[d] Round 1, n=20; Round 2, n=40; Round 3, n=35; Round 4, n=34; Round 5, n=35; Round 6, n=35; Round76, n=35

[e] For combination tests, pan or Pv line, only, positive indicates a false positive non *P. falciparum* infection (Round 1 n=316; Round 2, n=400; Round 3, n=396; Round 4, n=392; Round 5, n=400); Round 6, n=400; Round 7, n=400)

[f] Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=80; Round 2, n=160; Round 3, n=140; Round 4, n=136; Round 5, n=140; Round 6, n=140; Round 7, n=140)

[g] For combination tests, pan or Pv line, only, positive indicates a false positive non-*P. falciparum* infection (Round 1, n=158, Round 2, n=200; Round 3, n=198; Round 4, n=196; Round 5, n=200; Round 6, n=200; Round 7, n=200)

[h] Pf line positive indicates a false positive *P. falciparum* infection (Round 1, n=40; Round 2, n=80, Round 3, n=70; Round 4, n=68; Round 5, n=70; Round 6, n=70; Round 7, n=70)

[i] Round 1, n=168; Round 2, n=200; Round 3, n=200; Round 4, n=232; Round 5, n=236; Round 6, n=208; Round 7, n=220

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

[k] PDS presented in the table is based on a positive Pf test line (either HRP2 or Pf-pLDH). The results in brackets are the PDS based alone on HRP2 and Pf-pLDH test lines, respectively.

[l] Round 1, n=954; Round 2, n=1240; Round 3, n=1204; Round 4, n=1192; Round 5, n=1214 ; Round 6, n=1210; Round 7, n=1210

[m] Indicates a WHO prequalified product

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

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

Table S3: Malaria RDT rounds 4–7 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µl). Positivity rate at baseline (room temperature) and after 60 days incubation at room temperature, 35°C and 45°C

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf only tests															
ABON™ Malaria P.f. Rapid Test Device (Whole Blood)	IMA-402	ABON Biopharm (Hangzhou) Co. Ltd	15.0	15.0	17.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Adv Dx™ Malaria Pf Rapid Malaria Antigen Detection Test	RKMAL017	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
ADVANCED QUALITY™ ONE STEP Malaria (p.f) Test [a]	ITP11002-TC25	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Advantage P.f. Malaria Card	IR016025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Alere™ Malaria Ag P.f	05FK140-40-0	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Aspen® Malaria Ag Pf	AS0015	Aspen Laboratories Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
BIONOTE MALARIA P.f. Ag Rapid Test Kit	RG19-11	Bionote,Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
BioTracer™ Malaria P.f Rapid Card	17912	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria HRP2 (Pf)	RMOM(U)-XXX7X	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
CareStart™ Malaria Pf (HRP2) Ag RDT	RMOM-03091	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf (HRP2/pLDH) Ag RDT	RMPM(U)-XXX7X	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line [b]	RMSM-05071	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
careUS™ Malaria Pf (HRP2) Ag	RMO-M05082	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
DIAQUICK Malaria P.f. Cassette	W06200	DIALAB	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
EzDx™ Malaria Pf Rapid Malaria antigen detection test	RK MAL 008	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
First Response® Malaria Ag P. falciparum (HRP2) Card Test	I13FRC25	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
First Response® Malaria Ag P. falciparum (HRP2) Card Test	PI13FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
FirstSign™ Malaria Pf	2100CB-25	Unimed International Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f Antigen Test	ANMPF-7025	Humasis Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
ICT MALARIA P.F. CASSETTE TEST [a]	ML01	ICT INTERNATIONAL	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
IMMUNOQUICK® MALARIA falciparum	0502_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
KHB® Malaria Ag (HRP2) Pf Rapid Test	R-409-50-C	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
KHB® Malaria Ag P.f Rapid Test	KH-R-06-20	Shanghai Kehua Bio-engineering Co.,Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Malaria Antigen Test-Pf	MAG01040	Oscar Medicare Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
Malaria Pf Rapid Test	GCMAL(pf)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Maleriscan ® Malaria P.f Antigen Test	MAT-PF-50	Bhat Bio-Tech India (Pte.) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
GMD Malaria Pf test	GMDMALPF001	Medical Diagnostech (Pty) Ltd	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
One Step Malaria HRP2 (P.f) Test [a]	W37-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
One Step Malaria P.F Test (Cassette)	522352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
One Step Test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag	MPHRPD-01	Meril Diagnostics Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
OnSite Malaria Pf Ag Rapid Test	R0114C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
PALUTOP + pf®	5531	ALLDIAG SA	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Paracheck® Pf-Rapid Test for P.falciparum Malaria Device (Ver.3)	302030025	Orchid Biomedical Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Paracheck® Pf-Rapid Test for P.falciparum Malaria Dipstick (Ver.3)	302040025	Orchid Biomedical Systems	100.0	96.7	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Parahit f® Ver 1.0 - Dipstick [a]	55IC103-50	ARKRAY Healthcare Pvt Ltd c	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Parahit® f Ver 1.0 - Device [a]	55IC104-50	ARKRAY Healthcare Pvt Ltd c	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Rapid 1-2-3® Hema® Cassette Malaria PF	MAL-PF-CAS/25 (100)	Hema Diagnostic Systems	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
RapiGEN BIOCREDIT Malaria Ag Pf (HRPII)	C10RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
RightSign® Malaria P.f. Rapid Test Cassette (Whole Blood)	IMPF-C51	Hangzhou Biotest Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) [b]	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) 2 Lines	05FK130-40-0	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
SD BIOLINE Malaria Ag Pf	05FK50	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
Trusty™ Malaria Antigen P.f. test	A03-01-322	Artron Laboratories Inc.	100.0	100.0	56.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4

Table S3 *(continued)*

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Pf and Pan															
ABON™ Plus Malaria P.f/Pan Rapid Test Device (Whole Blood)	IMA-T402	ABON Biopharm (Hangzhou) Co. Ltd	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
ACCUCARE ONE STEP MALARIA Pf/Pan Antigen Test	MAGC 25	LAB-CARE Diagnostics (India) PVT. LTD.	83.3	73.3	10.0	100.0	100.0	100.0	3.3	10.0	0.0	70.0	90.0	30.0	5
Adv Dx™ Malaria Pan/Pf Rapid Test Detection Kit	RKMAL016	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	7
Advanced Quality™ Rapid Malaria Test (Pf/Pan)	ITP11005	InTec Products, Inc.	86.7	96.7	100.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5
Advantage Mal Card	IR221025	J. Mitra & Co. Pvt. Ltd.	0.0	0.0	0.0	100.0	100.0	100.0	0.0	0.0	0.0	70.0	100.0	80.0	5
Advantage Malaria Pan + Pf Card	IR231025	J. Mitra & Co. Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	93.3	26.7	100.0	100.0	100.0	5
Alere Trueline™ – Rapid test kit for Malaria Ag Pf/Pan (HRP-II/pLDH)	05FK60AI-40	Alere Medical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	46.7	70.0	33.3	100.0	100.0	100.0	7
AllTest™ Malaria P.f./Pan Rapid Test Cassette	IMPN-402	Hangzhou AllTest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	16.7	90.0	100.0	100.0	7
Asan Easy Test® Malaria Pf/Pan Ag [a]	AM4650-K	ASAN Pharmaceutical Co., Ltd	100.0	100.0	100.0	100.0	100.0	100.0	76.7	50.0	10.0	100.0	100.0	100.0	7
Aspen® Malaria Ag Pf/Pv	AS0060	Aspen Laboratories Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	50.0	90.0	100.0	100.0	100.0	100.0	7
ATOMORAPID™ MALARIA (PF/PAN)	MMAL01	Atomo Diagnostics PTY Limited	100.0	100.0	100.0	100.0	100.0	100.0	0.0	16.7	0.0	100.0	100.0	100.0	6
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device [b]	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
BIOCREDIT Malaria Ag Pf/Pan (HRPII/pLDH) [a]	C32RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	80.0	26.7	6.7	100.0	100.0	100.0	7
BIONOTE MALARIA P.f.& Pan Ag Rapid Test Kit [a]	RG19-08	Bionote,Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	6
Biosynex® Malaria Pf/Pan	0584_K25	Biosynex	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	7
BioTracer™ Malaria P.f/PAN Rapid Card	17012	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	70.0	100.0	100.0	100.0	7
CareStart™ Malaria Pf/PAN (pLDH) Ag RDT [a]	RMLM-05071	Access Bio, Inc.	100.0	96.7	93.3	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	7
CareStart™ Malaria Pf/PAN (HRP2/pLDH) Ag COMBO RDT	RMRM(U)-XXX7X	Access Bio, Inc.	100.0	100.0	96.7	100.0	100.0	100.0	93.3	86.7	53.3	100.0	100.0	100.0	5
CareStart™ Malaria Screen RDT [a]	RMAM-05071	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	7
Core Malaria Pan Pf	MAL-190024	Core Diagnostics Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	26.7	80.0	83.3	100.0	100.0	100.0	4
DIAQUICK Malaria P.f/Pan Cassette	Z11200CE	DIALAB GmbH	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	80.0	5
EzDx™ Malaria Pan/Pf Rapid test detection Kit	RK MAL 001	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	3.3	23.3	10.0	100.0	100.0	100.0	6
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	I16FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	10.0	0.0	100.0	100.0	100.0	5
First Response® Malaria Ag. pLDH/HRP2 Combo Card Test	PI16FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	70.0	100.0	100.0	100.0	6
FirstSign™ ParaView (Pan+Pf)	2101CB-25	Unimed International Inc.	96.7	100.0	100.0	100.0	100.0	100.0	0.0	0.0	13.3	100.0	100.0	100.0	4
GenBody™Malaria Pf/Pan Ag	MALAG100	GenBody Inc.	100.0	100.0	93.3	100.0	100.0	100.0	0.0	0.0	0.0	50.0	100.0	10.0	5
Genedia® Malaria P.f/Pan Ag Rapid Test	20-0146-01	Green Cross Medical Science Corp. (Korea)	100.0	100.0	43.3	100.0	100.0	100.0	3.3	0.0	13.3	0.0	0.0	0.0	5
Humasis Malaria P.f/Pan Antigen Test	AMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
Humasis Malaria P.f/Pan Antigen Test	ANMAL-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	6
ICT MALARIA DUAL TEST [a]	ML03	ICT INTERNATIONAL	100.0	100.0	100.0	100.0	100.0	100.0	3.3	3.3	13.3	90.0	100.0	100.0	7
Is It... Malaria Pf PAN	MPFPAN050	Medsource Ozone Biomedicals Pvt. Ltd.	100.0	93.3	100.0	100.0	100.0	100.0	93.3	93.3	93.3	100.0	100.0	100.0	7
Is It... Malaria Pf/Pv Device	AL030	Medsource Ozone Biomedicals	100.0	100.0	96.7	100.0	100.0	100.0	93.1	96.6	36.7	100.0	100.0	90.0	6
Malaria pf (HRP II)/PAN (pLDH) Antigen Detection Test Device	1-13-101-1	United Biotech, Inc.	100.0	96.7	96.7	100.0	100.0	100.0	16.6	0.0	0.0	90.0	40.0	50.0	4
Malaria pf (pLDH) / PAN-pLDH Test Device	MFV-124	AZOG, Inc.	46.7	56.7	66.7	100.0	100.0	100.0	13.3	93.3	100.0	60.0	100.0	100.0	5
Malaria Pf./Pan Antigen (MAL Pf/Pan) Test Kit	A03-18-322	Artron Laboratories Inc.	10.0	6.7	0.0	100.0	100.0	100.0	10.0	3.3	0.0	100.0	100.0	90.0	5
Malaria Pf/ PAN	GM004	Genomix Molecular Diagnostics Pvt.Ltd.	56.7	23.3	26.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	90.0	50.0	4
Malaria Pf/Pan One Step Rapid Test	RT 20222	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	96.7	100.0	90.0	100.0	0.0	0.0	0.0	100.0	90.0	100.0	5
MeDiPro Malaria Ag HRP2/pLDH Combo	IR-0051K	Formosa Biomedical Technology Corp.	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	0.0	0.0	0.0	4
Meriscreen Malaria Pf/Pan Ag	MHLRPD-01	Meril Diagnostics Private Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	46.7	56.7	0.0	100.0	100.0	100.0	6
NanoSign Malaria pf/pan Ag 3.0	RMAP10	Bioland Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
NG-Test MALARIA Pf/Pan (pLDH)	NG-MAL-W23-001	SARL NG Biotech, Z.A.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	5

(continued)

Table S3: Malaria RDT rounds 4–7 heat stability results on a cultured *P. falciparum* sample at low (200) and high (2000) parasite density (parasites/µL). Positivity rate at baseline (room temperature) and after 60 days' incubation at 35°C and 45°C *(continued)*

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
NG-Test MALARIA Pf/Pan (pLDH)	NGB-MAL-W23-005	NG Biotech	100.0	100.0	100.0	100.0	100.0	100.0	53.3	86.7	66.7	100.0	100.0	100.0	7
One Step Malaria P.f/Pan Whole Blood Test	W62-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	96.7	100.0	100.0	100.0	0.0	0.0	0.0	90.0	100.0	70.0	6
OnSite Malaria Pf/Pan Ag Rapid Test	R0113C	CTK Biotech, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	6.7	0.0	100.0	100.0	100.0	6
ParaHIT - Total Ver. 1.0 (Device)	55IC204-10	Span Diagnostics Ltd. [d]	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	4
ParaHIT - Total Ver. 1.0 (Dipstick)	55IC203-10	Span Diagnostics Ltd. [d]	100.0	93.3	46.7	100.0	100.0	60.0	50.0	0.0	0.0	100.0	90.0	0.0	4
Parascreen® - Rapid test for Malaria Pan/Pf	503030025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	100.0	90.0	93.3	100.0	100.0	100.0	6
QuickProfile™ Malaria Pf/Pan Test	71063	Lumiquick Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	100.0	96.7	100.0	100.0	100.0	100.0	6
Rapid 1-2-3 HEMA® CASSETTE MALARIA PF/PAN	MAL-Pf/Pan-CAS/25	Hema Diagnostic Systems	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	33.3	100.0	100.0	100.0	7
RightSign™ Malaria P.f./Pan Rapid Test Cassette	IMPN-C52	Hangzhou Biotest Biotech Co. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	20.0	100.0	100.0	60.0	100.0	5
SD BIOLINE Malaria Ag P.f/Pan	05FK60	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	0.0	0.0	0.0	100.0	100.0	100.0	5
Vikia® Malaria Ag Pf/Pan	412499	IMACCESS S.A.S	100.0	96.7	96.7	100.0	100.0	100.0	0.0	0.0	0.0	60.0	60.0	0.0	5
Pf and Pv/Pvom															
ADVANCED QUALITY™ ONE STEP Malaria (p.f/p.v.) Tri-line Test [a]	ITP11003-TC25	InTec Products, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
BIOCREDIT Malaria Ag Pf/Pv (pLDH/pLDH)	C60RHA25	RapiGEN Inc.	93.3	86.7	58.6	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Biosynex® Malaria Pf/Pv	0581_K25	Biosynex	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
BioTracer™ Malaria P.f/P.v Rapid Card	17412	Bio Focus Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag Combo RDT	RMVM-03091	Access Bio Ethiopia	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf/Pv (HRP2/pLDH) Ag. Combo RDT [a]	RMVM-05072	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
careUS™ Malaria Combo Pf/Pv (HRP2/pLDH) Ag	RMV-M05082	WELLS BIO, INC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Coretests® One Step Malaria Pf/Pv Ag Test Device	B42-21/B42-22	Core Technology Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
EzDx™ Malaria Pv/Pf Rapid Malaria antigen detection test	RK MAL 003	Advy Chemical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
FalciVax™ - Rapid Test for Malaria Pv/Pf	503010025	Zephyr Biomedicals	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
First Response® Malaria Ag Pf/Pv Card Test	PI19FRC	Premier Medical Corporation Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
HiSens Malaria Ag P.f/P.v Combo Card	HR3123	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
HiSens Malaria Ag P.f/VOM Combo Card	HR3323	HBI Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f/P.v Antigen Test	AMFV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Humasis Malaria P.f/P.v Antigen Test	ANMIV-7025	Humasis, Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
KHB® Malaria Ag P.f/P.v Rapid Test	KH-R-07-50	Shanghai Kehua Bio-engineering Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	1-13-101-3	United Biotech, Inc.	100.0	100.0	100.0	90.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria Pf (HRPII)/ PV (PLDH) Antigen Detection Test Device	GM006	Genomix Molecular Diagnostics Pvt. Ltd.	83.3	90.0	83.3	100.0	90.0	70.0	NA	NA	NA	NA	NA	NA	5
Malaria Pf/Pv	GM002	Genomix Molecular Diagnostics Pvt.Ltd.	40.0	33.3	40.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Malaria Pf/Pv Rapid Test	GCMAL(pf/pv)-402a	Zhejiang Orient Gene Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Malaria PV/PF (pLDH/HRP2) Antigen Test	Inf-72	Nantong Egens Biotechnology Co., Ltd.	100.0	100.0	96.6	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
Maleriscan® Malaria Pf/PAN (Pv, Pm, Po) 3 Line Antigen Test	MAT-PF/PAN-50	Bhat Bio-Tech India (P) Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
One Step Malaria HRP2/pLDH (P.f/P.v) Test [a]	W056-C	Guangzhou Wondfo Biotech Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
One Step Malaria P.F/P.V Test (Cassette)	523352	Blue Cross Bio-Medical (Beijing) Co., Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	5
One Step Test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag	MFLRPD-02	Meril Diagnostics Pvt. Ltd.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
OnSite Malaria Pf/Pv Ag Rapid Test	R0112C	CTK Biotech, Inc.	100.0	100.0	90.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
ParaHIT®fV Rapid test for P. falciparum and P.vivax Malaria - Device	55IC402-50	Span Diagnostics Ltd. [d]	100.0	96.7	96.7	100.0	100.0	90.0	NA	NA	NA	NA	NA	NA	5
QuickProfile™ Malaria Pf/Pv Antigen Test [a]	71050	Lumiquick Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
RAPID 1-2-3® HEMA CASSETTE MALARIA PF/PV TEST	MAL-PFV-CAS/25(100)	Hema Diagnostic Systems, LLC	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
RapiGEN BIOCREDIT Malaria Ag Pf/Pv (HRPII/pLDH)	C40RHA25	RapiGEN Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD Bioline Malaria Ag P.f/P.v	05FK80	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6

Table S3 *(continued)*

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pan line)			Positive test results for *P. falciparum* (Pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
Rapid Test Kit for Malaria Ag Pf/Pv - Alere Trueline Malaria Ag Pf/Pv	11108191040	Alere Medical Private Limited	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
Trusty™ Malaria Antigen P.f./p.v. test	A03-12-322	Artron Laboratories Inc.	100.0	100.0	36.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	4
Pf, Pf and Pv															
SD Bioline Malaria Ag P.f/P.f/P.v [b]	05FK120	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
Pf, Pv and Pan															
PALUTOP +4 optima®	5499	ALLDIAG SA	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	7
Pan Only															
Advantage Pan Malaria Card	IR013025	J. Mitra & Co. Pvt. Ltd.	NA	NA	NA	NA	NA	NA	36.7	66.7	60.0	100.0	100.0	90.0	5
AZOG hCG Malaria Detection Test Device	MPT-124	AZOG, INC.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	4
CareStart™ Malaria PAN (pLDH) Ag RDT	RMNM(U)-XXX7X	Access Bio, Inc.	NA	NA	NA	NA	NA	NA	100.0	100.0	100.0	100.0	100.0	100.0	5

NA, not applicable

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

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

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

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

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

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

Product	Product code	Manufacturer	Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (Pf line)			Positive test results for *P. falciparum* (pan line)			Positive test results for *P. falciparum* (pan line)			Round
			200 parasites/µl			2000 parasites/µl			200 parasites/µl			2000 parasites/µl			
			Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	Baseline	35°C	45°C	
			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			Percentage of tests positive			
			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			Lots 1 and 2 combined			
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - (Pf(HRP2) line)	RMSM-05071	Access Bio, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	7
CareStart™ Malaria Pf (HRP2/pLDH) Ag Combo 3-Line - (Pf(pLDH) line)			100.0	50.0	50.0	100.0	50.0	50.0	NA	NA	NA	NA	NA	NA	7
SD Bioline Malaria Ag P.f/P.f/P.v - (PF(HRP2) line)	05FK120	Standard Diagnostics, Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD Bioline Malaria Ag P.f/P.f/P.v - (PF(pLDH) line)			30.0	30.0	30.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH) - (PF(HRP2) line)	05FK90	Standard Diagnostics Inc.	100.0	100.0	100.0	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
SD BIOLINE Malaria Ag P.f. (HRP2/pLDH)- (PF(pLDH) line)			93.3	90.0	66.7	100.0	100.0	100.0	NA	NA	NA	NA	NA	NA	6
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(HRP2) line)	MFV-124F	AZOG, INC.	96.7	96.7	100.0	100.0	100.0	100.0	3.3	0.0	0.0	20.0	0.0	0.0	4
AZOG Malaria pf (HRPII)/pf (LDH)/ (PAN-LDH) Antigen Detection Device - (PF(pLDH) line)			13.3	3.3	6.7	50.0	10.0	50.0	3.3	0.0	0.0	20.0	0.0	0.0	4

Table S4: Products evaluated during rounds 1–7 that have been removed from summary results listings

Manufacturer	Product name	Product code
Amgenix International, Inc.	OnSight™ - Malaria Pf Test	511-25-DB
	OnSight™ - ParaQuick-2 (Pv,Pf) Malaria Test	537-25-DB
	OnSight™ - PanScreen (Pan) Malaria Test	539-25-DB
	OnSight™ - ParaQuick (Pan, Pf) Test	536-25DB
Abon Biopharm (Hangzhou) Co. Ltd. (Iverness Medical)	ABON Malaria Pan/P.f.Rapid Test Device (whole blood)	IMA-B402
Access Bio, Inc.	CareStart™ Malaria/Pregnancy (HRP2/pLDH/ HCG)	RRHM(U)-XXX7X[a]
Access Bio Ethiopia	ParaCare Malaria HRP2/pLDH (Pf/Pv) COMBO	G0161
	ParaCare Malaria HRP2/pLDH (Pf/VOM) COMBO	G0171
ACON Biotech (Hangzhou) Co. Ltd	Surestep™ Malaria Pf/Pan Rapid Test Device (Whole Blood)	IMA-T402
Acon Laboratories, Inc	Malaria Plasmodium falciparum Rapid Test Device (Whole Blood)	IMA-402
AZOG, Inc	Malaria pf (HRP II) / pv (pLDH) Antigen Detection Test Device	MFV-124V
	Malaria pf (HRP II) / (PAN-LDH) Antigen Detection Test Device	MFV-124R
Bhat Bio-Tech India (P) Ltd	Maleriscan® Malaria Pf/Pv	MAT-50
Bioland, Ltd	Nano Sign Malaria Pf Ag	RMAF10
	NanoSign Malaria Pf/Pv Ag	RMAD10
BioNote,Inc.	BIONOTE MALARIA P.f&P.v Ag Rapid Test Kit	RG19-12
Biosynex	IMMUNOQUICK CONTACT falciparum	0519K25
	Immunoquick Malaria +4	0506_K25
	IMMUNOQUICK CONTACT Malaria +4	0525K25
Core Diagnostics	Core™ Malaria Pf	MAL-190020
	Core™ Malaria Pv/Pf	Mal-190022
	Core™ Malaria Pan/Pv/Pf	Mal-190026
CTK Biotech, Inc.	OnSite Pf Ag Rapid Test	R0114C
DiaMed - A Division of Bio-Rad	OptiMAL-IT	710024
Dima • Gesellschaft für Diagnostika mbH	Malaria Pan test	MAL-W23N-001
Diagnostics Automation/Cortez Diagnostics Inc.	Malaria P.F/Vivax	172110P-25
Guangzhou Wondfo Biotech Co. Ltd.	One Step Malaria P.f./Pan Whole Blood Test	W56-C
HBI Co., Ltd.	HiSens Malaria Ag P.f/P.v Card	HR2823
	HiSens Malaria Ag Pf/Pv (HRP2/pLDH) Card	HR2923
	HiSens Malaria Ag Pf HRP2 Card	HR3023
Human GmbH	Hexagon Malaria	58051
	Hexagon Malaria Combi	58024
ICT INTERNATIONAL	ICT Malaria Combo	ML02
	ICT MALARIA P.F.	ML04
IND Diagnostic Inc.	One Step Malaria Antigen Strip	820-1
	IND ONE STEP MALARIA ANTIGEN P.f/Pan TEST	535-10
	IND ONE STEP MALARIA ANTIGEN P.f	535-11
Innovatek Medical Inc.	Quickstick Malaria Antigen Test	
Inverness Medical Innovations, Inc.	Binax Now Malaria	IN660050
J. Mitra & Co. Pvt. Ltd.	Advantage Malaria Card	IR211025
Medical Diagnostech (Pty) Ltd	MD Malaria Pf/Pan(pLDH) test	MDMALLDH001
Medisensor, Inc.	Medisensor Malaria HRP2/pLDH (Pf/Pv) COMBO	M161
	Medisensor Malaria HRP2/pLDH (Pf/VOM) COMBO	M171
Orgenics Ltd. (Inverness Innovations)	Clearview® Malaria pLDH	70884025
Orgenics Ltd.(IS)	Clearview® Malaria Dual	VB20
Premier Medical Corporation Ltd.	First Response® Malaria Ag pLDH	I12FRC30
RapiGen inc.	BIOCREDIT Malaria pf(HRP II)	HR0100
Real World Diagnostics	Malaria Pf/PAN Test[X]	PROMALPFV001
Span Diagnostics	ParaHIT®-f Dipstick	551C010-50/25977
	ParaHIT®- f Device	551C102-50/25975
	ParaHIT - Total (Device)	55IC202-10/25989
	ParaHIT Pan M (dipstick)	55IC301-10
	ParaHIT total (dipstick)	55IC201-10/25988
SSA Diagnostics & Biotech Systems	diagnosticks- Malaria (Pf) Cassette	KMFC6001
	diagnosticks- Malaria (Pf) Dipstick	KMFD6007
	diagnosticks- Malaria (Pv/Pf) Cassette	KMVFC6002
	diagnosticks MALARIA (Pan) Cassette	MPNWBC1007.3
	diagnosticks MALARIA (Pan/Pf) Cassette	MPNFWBC1007.4
	diagnosticks MALARIA (Pan/Pv/Pf) Cassette	MPNVFC1007.5
Standard Diagnostics Inc.	SD BIOLINE Malaria Ag	05FK40
	SD BIOLINE Malaria Ag Pf/ Pf/ Pv	05FK100
	SD BIOLINE Malaria Ag Pf/ Pan	05Fk66
	SD BIOLINE Malaria Ag Pv	05FK70
	SD BIOLINE Malaria Ag P.f/Pan	05FK63[b]
	SD BIOLINE Malaria Ag P.f/P.v	05FK83[c]
	SD BIOLINE Malaria Ag Pf	05FK53[d]
Unimed International	FirstSign – Malaria Pf Card Test	-
	FirstSign – ParaView-2 (Pv + Pf) Card Test	2102CB-25
	FirstSign™ - PanCheck (Pan) Malaria Test	2104 CB-25
	FirstSign™ - ParaView-3 (Pan+Pv+Pf) Malaria Test	2103 CB-25
Vision Biotech (Pty) Ltd	Vision Malaria Pf	VB01
	Clearview® Malaria Combo	VB11
Zephyr Biomedicals	Paramax-3 Rapid Test for Malaria Pan/Pv/Pf (device)	50320025

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

[a] Previously listed with product code G0221

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

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

[d] Previously co-listed with 05FK50(multi-use pack), but removed because single pack format (05FK53) not evaluated at CDC

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ANNEXES

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

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

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

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

Before each round of WHO malaria RDT product testing, the distribution of HRP2, pLDH and aldolase concentrations at 200 parasites/µL dilution of the wild-type *P. falciparum* and wild-type *P. vivax* samples selected for the phase-2 panels were systematically compared with those in the previous round to ensure there was no statistically significant difference. The figures and tables below show the distribution of antigen concentrations in all six performance evaluation panels. No statistically significant differences were seen (Kruskal-Wallis test; $p > 0.5$), confirming that the results of each new round are additive (and comparable) to the previous ones. In the following box and whisker plots, the end of whiskers represent minimum and maximum values; the box represents middle 50% of data and the line through box represents median values; the crosses represent the mean values.

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

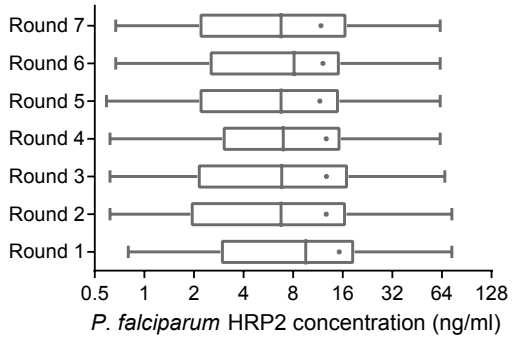


Figure AS1.2: Box-and-whisker plot of distribution of *P. falciparum* pLDH concentration (ng/mL) in product testing phase 2 (wildtype) panels.

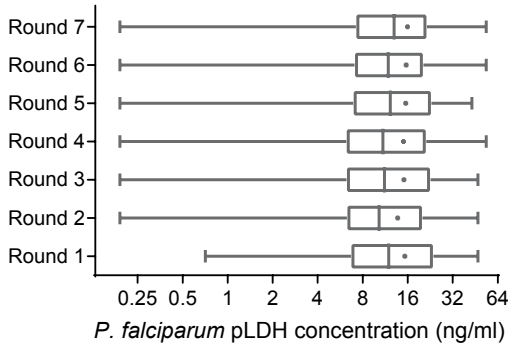


Figure AS1.3: Box-and-whisker plot of distribution of *P. vivax* pLDH concentration (ng/mL) in product testing phase 2 (wild-type) panels.

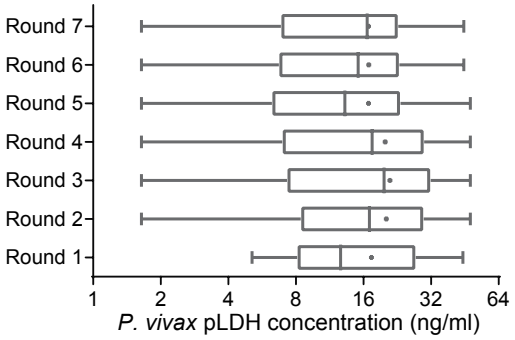


Figure AS1.4: Box-and-whisker plot of distribution of *P. falciparum* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

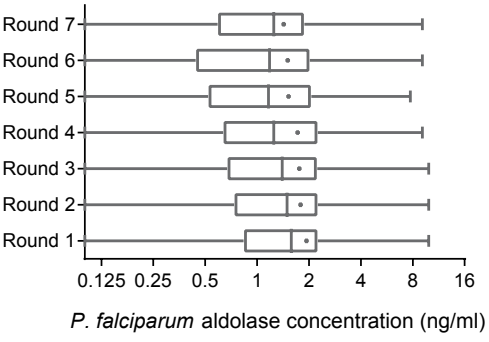


Figure AS1.5: Box-and-whisker plot of distribution of *P. vivax* aldolase concentration (ng/mL) in product testing phase 2 (wild-type) panels.

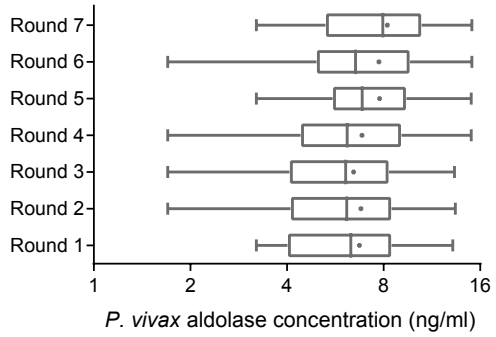


Table AS1.1: Statistics for *P. falciparum* HRP2 concentration (ng/mL) in product testing phase 2 (wild-type) panels.

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

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

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

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Number of values[a]	74	93	92	92	94	98	98
Minimum	0.71	0.19	0.19	0.19	0.19	0.19	0.19
25% percentile	6.68	6.27	6.23	6.20	6.90	7.04	7.20
Median	11.95	10.31	11.18	10.92	12.24	11.85	12.99
75% percentile	23.75	20.10	22.70	21.28	23.05	20.36	21.51
Maximum	47.15	47.15	47.15	53.53	43.02	53.53	53.53
Mean	15.31	13.71	15.08	14.97	15.53	15.61	15.93
Std. Deviation	11.47	10.90	11.72	11.98	11.43	12.00	11.60

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

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

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Number of values[a]	20	37	33	32	34	34	35
Minimum	5.10	1.64	1.64	1.64	1.64	1.64	1.64
25% percentile	8.10	8.40	7.30	6.96	6.26	6.72	6.86
Median	12.65	17.00	19.78	17.50	13.22	15.17	16.62
75% percentile	27.40	29.69	31.89	29.84	23.42	23.14	22.89
Maximum	44.40	47.90	47.90	47.90	47.90	44.79	44.79
Mean	17.38	20.24	20.99	20.00	16.84	16.90	16.87
Std. Deviation	11.57	13.27	13.55	13.00	12.59	11.78	11.17

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

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

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Number of values[a]	77	98	99	97	98	99	99
Minimum	0.00	0.00	0.00	0.00	0.00	0.00	0.00
25% percentile	0.84	0.74	0.67	0.64	0.52	0.44	0.59
Median	1.58	1.49	1.40	1.25	1.17	1.18	1.25
75% percentile	2.25	2.25	2.23	2.25	2.07	2.02	1.88
Maximum	9.90	9.90	9.90	9.08	7.74	9.08	9.08
Mean	1.93	1.79	1.76	1.72	1.52	1.50	1.43
Std. Deviation	1.73	1.66	1.69	1.68	1.52	1.61	1.34

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

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

	Round 1	Round 2	Round 3	Round 4	Round 5	Round 6	Round 7
Number of values[a]	20	40	34	33	35	35	35
Minimum	3.21	1.70	1.70	1.70	3.21	1.70	3.21
25% percentile	4.02	4.11	4.07	4.41	5.55	4.94	5.27
Median	6.33	6.15	6.10	6.16	6.86	6.54	7.96
75% percentile	8.47	8.47	8.32	9.10	9.43	9.68	10.52
Maximum	13.15	13.40	13.30	15.00	15.00	15.08	15.08
Mean	6.73	6.81	6.45	6.86	7.78	7.74	8.22
Std. Deviation	2.89	3.15	2.90	3.23	3.30	3.69	3.61

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

Annex S2: Malaria RDT field assessment and anomalies

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

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

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

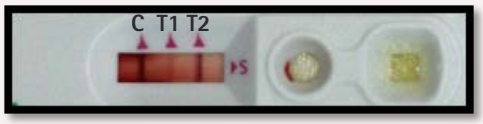
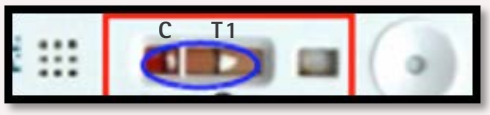
Date of assessment				
Commercial name				
Product code				
Lot number(s)				
	Yes	**No**	**NA**	**Problems /Comments**
Packaging and accessories				
The RDT box is in good condition				
RDTs are in individual sealed package				
The correctly indicated number of RDTs are in the box				
Desiccant is included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

NA, not applicable

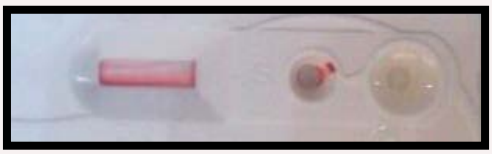
Figure AS2.1 illustrates examples of RDT observations/anomalies encountered and routinely recorded during round 6 of WHO Malaria RDT Product Testing at the CDC. In most cases, these anomalies do not invalidate the results, as reactivity in the control and test line areas are still visible, but they may pose challenges to health workers interpreting the results. Furthermore, they should be reported to manufacturers.

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

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

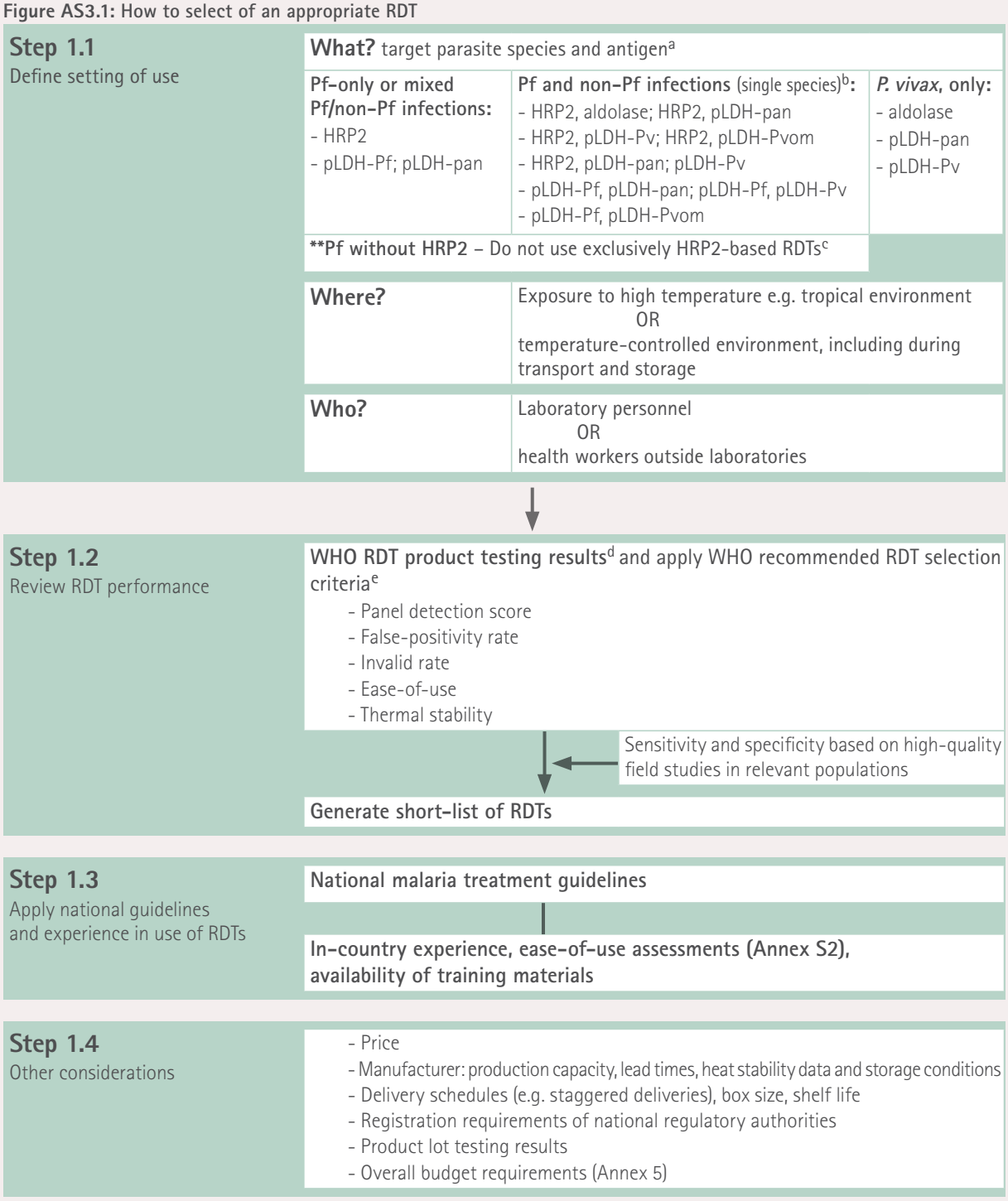
a) Observations on the test strip		
Red background		Background staining is relatively common. In this example, the result is positive as test lines are positive; however, a more intense red background may obscure weak positive test lines, giving false-negative results.
Incomplete clearing		In this example,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

d) RDT structural problems

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

Annex S3: Selection of an appropriate RDT

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



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

[b] Tests with a *P. falciparum*-specific line and pan-specific line will not distinguish *P. falciparum*-only infections from mixed *P. falciparum* infections. Distinguishing *P. falciparum* from mixed *P. falciparum-vivax* infections is important only if a full course of primaquine is routinely given for infections due to *P. vivax*. This must be weighed against the loss of ability to detect *P. malariae* and *P. ovale* if a test has only *P. falciparum*- and *P. vivax*-specific lines. Inclusion of further test lines (e.g. Pf-Pv-pan-pLDH) to detect these increases the complexity of test interpretation. A programme should prioritize these various advantages and disadvantages according to local conditions in the initial stage of making procurement decisions.

[c] *P. falciparum* parasites lacking HRP2 +/- HRP3 genes have been identified with high frequency in parts of South America, Africa (Eritrea, Democratic Republic of the Congo, Ghana) and India (*1–6*).

[d] See references *(7–12)*.

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

For a comprehensive guide to procurement of malaria RDTs extending beyond selection to quantification, budgeting, technical specifications, management of tenders, contracts, supply management and monitoring of supplier performance and managing product variations, see reference in the full report *(16)*.

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