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Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

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**ABSTRACT**

**Background**

In settings where both *Plasmodium vivax* and *Plasmodium falciparum* infection cause malaria, rapid diagnostic tests (RDTs) need to distinguish which species is causing the patients’ symptoms, as different treatments are required. Older RDTs incorporated two test lines to distinguish malaria due to *P. falciparum*, from malaria due to any other *Plasmodium* species (non-falciparum). These RDTs can be classified according to which antibodies they use: Type 2 RDTs use HRP-2 (for *P. falciparum*) and aldolase (all species); Type 3 RDTs use HRP-2 (for *P. falciparum*) and pLDH (all species); Type 4 use pLDH (from *P. falciparum*) and pLDH (all species).

More recently, RDTs have been developed to distinguish *P. vivax* parasitaemia by utilizing a pLDH antibody specific to *P. vivax*.

**Objectives**

To assess the diagnostic accuracy of RDTs for detecting non-falciparum or *P. vivax* parasitaemia in people living in malaria-endemic areas who present to ambulatory healthcare facilities with symptoms suggestive of malaria, and to identify which types and brands of commercial test best detect non-falciparum and *P. vivax* malaria.

**Search methods**

We undertook a comprehensive search of the following databases up to 31 December 2013: Cochrane Infectious Diseases Group Specialized Register; MEDLINE; EMBASE; MEDION; Science Citation Index; Web of Knowledge; African Index Medicus; LILACS; and IndMED.

**Selection criteria**

Studies comparing RDTs with a reference standard (microscopy or polymerase chain reaction) in blood samples from a random or consecutive series of patients attending ambulatory health facilities with symptoms suggestive of malaria in non-falciparum endemic areas.
Data collection and analysis
For each study, two review authors independently extracted a standard set of data using a tailored data extraction form. We grouped comparisons by type of RDT (defined by the combinations of antibodies used), and combined in meta-analysis where appropriate. Average sensitivities and specificities are presented alongside 95% confidence intervals (95% CI).

Main results
We included 47 studies enrolling 22,862 participants. Patient characteristics, sampling methods and reference standard methods were poorly reported in most studies.

RDTi detecting 'non-falciparum' parasitaemia
Eleven studies evaluated Type 2 tests compared with microscopy, 25 evaluated Type 3 tests, and 11 evaluated Type 4 tests. In meta-analyses, average sensitivities and specificities were 78% (95% CI 73% to 82%) and 99% (95% CI 97% to 99%) for Type 2 tests, 78% (95% CI 69% to 84%) and 99% (95% CI 98% to 99%) for Type 3 tests, and 89% (95% CI 79% to 95%) and 98% (95% CI 97% to 99%) for Type 4 tests, respectively. Type 4 tests were more sensitive than both Type 2 (P = 0.01) and Type 3 tests (P = 0.03).

Five studies compared Type 3 tests with PCR; in meta-analysis, the average sensitivity and specificity were 81% (95% CI 72% to 88%) and 99% (95% CI 97% to 99%) respectively.

RDTs detecting Plasmodium vivax parasitaemia
Eight studies compared pLDH tests to microscopy; the average sensitivity and specificity were 95% (95% CI 86% to 99%) and 99% (95% CI 99% to 100%), respectively.

Authors’ conclusions
RDTs designed to detect P. vivax specifically, whether alone or as part of a mixed infection, appear to be more accurate than older tests designed to distinguish P. falciparum malaria from non-falciparum malaria. Compared to microscopy, these tests fail to detect around 5% of P. vivax cases. This Cochrane Review, in combination with other published information about in vitro test performance and stability in the field, can assist policy-makers to choose between the available RDTs.

Plain Language Summary
Rapid tests for diagnosing malaria caused by Plasmodium vivax or other less common parasites
This review summarises trials evaluating the accuracy of rapid diagnostic tests (RDTs) for diagnosing malaria due to Plasmodium vivax or other non-falciparum species. After searching for relevant studies up to December 2013, we included 47 studies, enrolling 22,862 adults and children.

What are rapid tests and why do they need to be able to distinguish Plasmodium vivax malaria
RDTs are simple to use, point of care tests, suitable for use in rural settings by primary healthcare workers. RDTs work by using antibodies to detect malaria antigens in the patient’s blood. A drop of blood is placed on the test strip where the antibodies and antigen combine to create a distinct line indicating a positive test.

Malaria can be caused by any one of five species of Plasmodium parasite, but P. falciparum and P. vivax are the most common. In some areas, RDTs need to be able to distinguish which species is causing the malaria symptoms as different species may require different treatments. Unlike P. falciparum, P. vivax has a liver stage which can cause repeated illness every few months unless it is treated with primaquine. The most common types of RDTs for P. vivax use two test lines in combination; one line specific to P. falciparum, and one line which can detect any species of Plasmodium. If the P. falciparum line is negative and the ‘any species’ line is positive, the illness is presumed to be due to P. vivax (but could also be caused by P. malariae, or P. ovale). More recently, RDTs have been developed which specifically test for P. vivax.

What does the research say
RDTs testing for non-falciparum malaria were very specific (range 98% to 100%) meaning that only 1% to 2% of patients who test positive would actually not have the disease. However, they were less sensitive (range 78% to 89%), meaning between 11% and 22% of people with non-falciparum malaria would actually get a negative test result.
RDTs which specifically tested for *P. vivax* were more accurate with a specificity of 99% and a sensitivity of 95%, meaning that only 5% of people with *P. vivax* malaria would have a negative test result.

**BACKGROUND**

**Target condition being diagnosed**

Malaria is a life-threatening illness caused by protozoan *Plasmodium* parasites, which are transmitted by many species of *Anopheles* mosquitoes. In 2008, there were between 190 and 311 million cases of malaria worldwide (WHO 2009b). The two most common species of parasites that cause malaria are *Plasmodium falciparum* and *Plasmodium vivax*. Falciparum malaria is the most common cause of severe malaria and malaria deaths and can also cause other complications, such as anaemia and, in pregnancy, low birthweight babies. Vivax malaria is a relapsing form, which is rarely fatal but can cause serious anaemia in children. Other, less common, *Plasmodium* species that cause malaria in people include *P. malariae* and *P. ovale*. Malaria is a curable disease, and therefore malaria-related morbidity and mortality can be reduced. Early, prompt and accurate diagnosis followed by appropriate treatment is the key to effective disease management (WHO 2003) and is a basic tenet of current malaria control policy (WHO 2005; Bell 2006).

People who are exposed repeatedly to *Plasmodium* infection develop a partial and incomplete immunity. This means that in highly endemic areas those most at risk are children under the age of five, who have not yet had the chance to develop immunity. In less endemic areas, or areas of seasonal or epidemic transmission, older children and adults are also at risk due to less developed immunity. Travellers from non-endemic to endemic countries are at highest risk because they have no immunity at all.

**Index test(s)**

Rapid diagnostic tests (RDTs) (WHO 2003) detect parasite-specific antigens in a drop of fresh blood through lateral flow immunochromatography (WHO 2006). The World Health Organization (WHO) currently lists 96 commercially available test kits meeting ISO131485 manufacturing standards (WHO 2009). RDTs do not require a laboratory or any special equipment (WHO 2006), are simple to use and can give results as a simple positive or negative result, at thresholds pre-set by the manufacturers, within 15 minutes (Talman 2007). Therefore, RDTs are, in general, suitable for remote areas with limited facilities and relatively untrained staff. However, they have a limited shelf life and need to be kept dry and away from temperature extremes. They may also fail to detect malaria where there are low levels of *Plasmodium* parasites in the blood, for example in young children with low immunity, and false positives are possible due to cross reactions or gametocytæmia (Kakkilaya 2003).

Different types of RDT use different types of antibody or combination of antibodies to detect *Plasmodium* antigens. Some antibodies aim to detect a particular species while others are pan-malarial, aiming to detect all types of *Plasmodium*. Table 1 lists the main types of RDT that were available in 2010. Since this classification was developed, the following test types have also become available:

- Pan pLDH only, with possible results of: no malaria; *P. falciparum* (Pf), *P. vivax* (Pv), *P. ovale* (Po), or *P. malariae* (Pm); invalid
- *P. vivax* specific pLDH only, with possible results of: no malaria; Pv; invalid;
- *P. falciparum* specific HRP-2 and *P. vivax* specific pLDH, with possible results of: no malaria; Pf, Pv, Pf + Pv; invalid.

HRP-2 can stay in the blood for 28 days after initiating the antimalarial therapy (Kakkilaya 2003). Because of this ‘persistent anti-gamaemia’, it is not possible to use these tests in assessing parasite clearance following treatment, and false positive results may be found in patients who have recently been treated for malaria. In contrast, pLDH is rapidly cleared from the blood following parasite death; in fact it may clear more rapidly than the dead parasites (WHO 2009).

**Alternative test(s)**

Microscopic examination of Giemsa-stained thick and thin blood films remains the conventional laboratory method and is still regarded as the ‘gold standard’. Microscopic examination provides a good sensitivity and specificity, and it allows species and stage differentiations and quantification of parasites, all of which are important in assessing the disease severity and prescribing appropriate therapy. Intensive examination is more likely to reveal parasitaemia so the test is carried out with a fixed number of fields examined. Infections may be missed if slides are not examined carefully (Wongsrichanalai 2007). Very low parasitaemia may be
missed even by good quality microscopy; the limit of detection of thick smear microscopy has been estimated at approximately four to 20 asexual parasites per µL, although under field conditions a threshold of 50 to 100 asexual parasites per µL is more realistic (Wongsrichanalai 2007). False positive results are also possible; if blood slides are not prepared carefully, artefacts may be formed which can be mistaken for Plasmodium parasites (Wongsrichanalai 2007).

The polymerase chain reaction (PCR), which is a molecular method based on DNA amplification, is the most accurate method of detecting parasites in the blood. Compared to microscopy, PCR is less prone to observer error and more sensitive at low levels of parasitaemia (Snounou 1993). For PCR, the limit of detection may be as low as 0.004 asexual parasites per µL (Hänscheid 2002).

However, whether this increased ability to detect low level parasitaemia makes it a better diagnostic test is uncertain, as sub-microscopic parasitaemia are of unknown clinical significance and the prevalence of asymptomatic sub-microscopic infection is high in some areas (May 1999). PCR is currently not widely available due to logistical constraints and the need for specially trained technicians and a well-equipped laboratory. It is usually used only for research purposes.

**Rationale**

A diagnostic test which is simple to perform, rapid and accurate is important in many situations to ensure prompt specific treatment, reduce misdiagnosis of non-malarial illness as malaria, limit the development of drug resistance (Talman 2007) and reduce drug wastage. The WHO lists some of the situations where RDTs can be particularly useful in remote areas without access to expert microscopy, complex emergencies and severe malaria, where rapid diagnosis is essential to save lives (WHO 2000).

The WHO 2010 guidelines recommend chloroquine for *P. vivax* malaria in areas in which parasites remain sensitive to this drug, although they are currently considering recommending artemisinin-based combination therapies (ACTs) for all *P. vivax* infections as they are effective (Gogtay 2013). Primaquine may be added to immediate treatment of *P. vivax* (and *P. ovale*) to effect a radical cure and prevent relapse (WHO 2010). Therefore, in areas where both *P. falciparum* and *P. vivax* are endemic, it is often useful to be able to distinguish between the two species.

The relative costs of microscopy and RDTs vary according to context. Where there is a relatively high prevalence of malaria and an established microscopy service, microscopy would usually be less expensive than RDTs because most of the costs associated with microscopy are fixed costs, and microscopy can also be used to diagnose other diseases. In areas where malaria is less prevalent, or very rural areas where access to good quality microscopy services is limited, RDTs may be less expensive than microscopy (WHO 2008). The cost of RDTs also depends on the type of test used, which will depend on the types of malaria parasite endemic in the area; the WHO describes three zones (WHO 2005a) as shown in Table 2.

RDTs may be used to confirm diagnosis before commencing treatment in people with symptoms of malaria where confirmation by microscopy is currently unavailable or unused, thereby increasing the specificity of diagnosis, which would otherwise be made on symptoms only. Alternatively, RDTs may replace microscopy for confirmatory diagnosis, where logistical factors and relative costs indicate that this may be beneficial. The usefulness of RDTs in these roles will depend to a large extent on their accuracy. The sensitivity and specificity thresholds that decide whether a test is useful in practice will depend upon the situation; as malaria endemicity varies enormously by geographic area, and positive and negative predictive values will vary considerably with endemicity, relating to the proportion of patients with fever who have malaria. In addition, microscopy is not a perfect reference standard in itself, and the relative accuracy of RDTs and microscopy will depend to a large extent on the performance of the laboratory facilities and personnel available for microscopy.

Previously published systematic reviews have focused on the accuracy of RDTs for diagnosing malaria in travellers returning to non-endemic countries from endemic countries (Marx 2005). As far as we know this is the first systematic review to assess the accuracy of the full range of RDTs for diagnosing non-falciparum or *P. vivax* malaria in people with symptoms in malaria-endemic areas. This review is the second of two Cochrane Reviews assessing the accuracy of RDTs for diagnosing symptomatic uncomplicated malaria in endemic countries. It covers two slightly different target conditions; non-falciparum malaria in the absence of *P. falciparum* infection and *P. vivax* malaria, corresponding to the results obtainable with different RDT test types. The first review reported separately on RDTs for diagnosing *P. falciparum* malaria (Abba 2011). The summaries in this review are to assist decision making, in conjunction with other relevant information about these tests, including in vitro assessment and tests of stability and costs (WHO 2012).

**OBJECTIVES**

To assess the diagnostic accuracy of RDTs for detecting non-falciparum or *P. vivax* malaria parasitaemia in people living in malaria-endemic areas who present to ambulatory healthcare facilities with symptoms suggestive of malaria and to identify which types and brands of commercial test best detect non-falciparum and *P. vivax* malaria.

**Investigation of sources of heterogeneity**

We planned to investigate heterogeneity in relation to age group, continent where the study took place, and adequacy of reference standard.
**METHODS**

**Criteria for considering studies for this review**

**Types of studies**

Studies sampling a consecutive series of patients, or a randomly selected series of patients were eligible. Where the report did not explicitly state that sampling was consecutive, but we judged that consecutive sampling was most probable, we included the report. We excluded studies if they did not present sufficient data to allow us to extract absolute numbers of true positives, false positives, false negatives and true negatives. Due to resource constraints, we also excluded studies if the report did not present enough information to allow full assessment of eligibility or if the study was reported only in a non-English language.

**Participants**

Studies recruiting people living in *P. vivax*, *P. ovale* or *P. malariae* endemic areas attending ambulatory healthcare settings with symptoms of uncomplicated malaria were eligible. We excluded studies if participants:

1. were non-immune people returning from endemic countries or were mainly recent migrant or displaced populations from non-endemic or very low endemicity areas;
2. had been treated for malaria and the test was performed to assess treatment outcome;
3. had symptoms of severe malaria;
4. did not have symptoms of malaria;
5. were recruited through active case finding (for example, door to door surveys).

In studies where only a subgroup of participants was eligible for inclusion in the review, we included the study provided that we could extract relevant data specific to that subgroup. If studies included some patients with severe malaria, and we could not extract data specific to a subgroup of participants with uncomplicated malaria, we included the study if 90% or more of the participants had uncomplicated malaria.

**Index tests**

Studies evaluating any immunochromatography-based RDTs specifically designed to detect non-falciparum or *P. vivax* malaria. We included commercial tests that are no longer available because they may use the same antibodies and very similar technology to tests that are currently available or may become available in the future. Older and more recently available versions of the same test, for example, OptiMAL and OptiMAL-IT were included separately. We also included prototype tests which are not longer available but which correspond to one of the commercial tests.

**Comparator tests**

We included studies regardless of whether they made comparisons with other RDT tests or not.

**Target conditions**

Studies aimed to detect non-falciparum or *P. vivax* malaria. Where no distinction was made by species, but over 98% of malaria infections were identified by the reference standard as non-falciparum or *P. vivax*, the study was eligible for inclusion.

**Reference standards**

Studies were required to diagnose non-falciparum or *P. vivax* malaria using at least one of the following two reference standards:

1. Conventional microscopy of thick blood smears, thin blood smears or both. Presence of asexual parasites of any density was regarded as a positive smear;
2. PCR.

The reference standard was required to be performed using blood samples drawn at the same time as those for the index tests. Where studies used more than one reference standard, we presented data relating to comparisons with each reference standard.

**Search methods for identification of studies**

We used a single search strategy for both Cochrane Reviews in this series (see Abba 2011).

**Electronic searches**

To identify all relevant studies, we used the search terms and strategy outlined in Appendix 1 to search the following databases: Cochrane Infectious Diseases Group Specialized Register; MEDLINE; EMBASE; MEDION; Science Citation Index; Web of Knowledge; African Index Medicus; LILACS; and IndMED. We based the search on the following MeSH, full text and keyword terms: Malaria, Plasmodium, reagent kits, diagnosis, diagnostics, RDT, dipstick, MRDD, OptiMal, Binax Now, Parasight, Immunochromatography, antigen detection, antigen test, Combo card. We did not limit the search by language or publication status (although we later excluded non-English language studies due to resource constraints). We restricted the searches to human studies. We updated the search on 31 December 2013.

**Searching other resources**

We searched the reference lists of included studies for relevant publications. Due to resource constraints, we did not search any other resources.
Data collection and analysis

Selection of studies

We initially used a single selection procedure to identify studies for inclusion in either of the two Cochrane Reviews in this series. The inclusion criteria differed between the reviews only in the target condition and parasite species. Therefore, of the study characteristics examined, we assessed parasite species last, for example a study listed as included due to not presenting sufficient data may also have not been a study of non-falciparum or *P. vivax* malaria. One author (KA) initially assessed the titles identified by the search, excluding those obviously irrelevant to the diagnosis of malaria using RDTs. We retained titles where we had any doubt regarding inclusion.

Based on abstract examination, we excluded irrelevant letters, review articles and articles and then excluded other irrelevant notes. Using a pro forma, two review authors (KA and NM) independently assessed the eligibility of the remaining potentially relevant articles based on full text publications. We have listed the excluded studies in the Characteristics of excluded studies table. We resolved any discrepancies by discussion. Where we could not reach agreement, we consulted a third author (PG or PO). Where it remained unclear whether a study was eligible for inclusion because of a lack of detail or poor reporting, we excluded it. Similarly, we excluded non-English language reports for logistical reasons.

We named studies according to the surname of the first study author and the year of publication. The study naming used in this review uniquely identifies multiple study cohorts within each study report (for example as 'Bell 2001a' and 'Bell 2001b'), each of which use different reference standards or present data separately for more than one population with different characteristics. More than one RDT may be evaluated in each study cohort, thus the number of test evaluations exceeds the number of study cohorts, which exceeds the number of study reports.

Data extraction and management

Two review authors (KA and NM) independently extracted data and resolved any discrepancies by discussion. In cases of studies where only a subgroup of participants met the review inclusion criteria, we extracted and presented data only for that particular subgroup. Where two versions of one reference standard were used, for example local clinic and expert standard microscopy, or field versus laboratory RDT testing, we only included the one most likely to yield the highest quality results.

For each study, we systematically extracted data on the characteristics of the study, as shown in Appendix 2. We also extracted data relating to the sensitivity of the RDT at different levels of parasitaemia (asexual parasites per µL of blood) as presented by the study authors. For each comparison of index test with reference test, we extracted data on the number of true positives, true negatives, false positives and false negatives in the form of a two by two table. RDT results are dichotomous; microscopy results were deemed positive at any level of asexual parasitaemia; and PCR results used the cut-off points presented by the study authors. Gametocyte-only parasitaemia was considered negative; where a study was unclear on how they had classed gametocyte-only parasitaemia, they were assumed to have used the same classification as ourselves and we included the data in the study.

We extracted data for each study (Smidt 2008), using current manufacturers' instructions in interpreting the RDT results. *P. falciparum* malaria only was considered as negative for parasitaemia. The target condition was defined slightly differently depending on the type of the test, as follows:

- Types 2, 3 and 4 - Non-falciparum malaria in the absence of falciparum malaria

RDT Types 2, 3 and 4 are designed to detect non-falciparum species (mainly *P. vivax* in most situations) when they occur without concurrent *P. falciparum* infection. They have two test lines, one specific for *P. falciparum* and one pan-malarial line to detect all malaria species. Non-falciparum malaria is identified by a positive pan-malarial line and negative *P. falciparum* line; mixed infections will produce positive results for both the *P. falciparum* and pan-malaria lines and are indistinguishable from *P. falciparum* alone.

Mixed infections detected by microscopy were considered true negative if RDT indicated *P. falciparum*; true positive if RDT indicated non-falciparum in the absence of *P. falciparum*; and false negative if RDT indicated no malaria. This method corresponded to the method most often described by the authors of the included studies, first described by Tjitra 1999.

- Tests using Pf HRP2 and Pv pLDH - *P. vivax* (whether alone or part of mixed infection)

These types of tests are designed to identify *P. vivax* parasitaemia specifically, as they have a test line specific to *P. vivax*. Some also include other test lines, specific to other types of malaria parasite. Test results were considered positive for *P. vivax* whether or not they also indicated the presence of *P. falciparum*.

Where study authors interpreted test results or presented data differently, we used all the information presented in the paper to extract data consistent with our own methods; if we were unable to do this, we did not include the data in the analyses.

Assessment of methodological quality

Three researchers (KA, NM and SJ) assessed the quality of each individual study using the checklist adapted from the QUADAS tool (Whiting 2003). We answered each question on the checklist with a yes or no response, or noted unclear if study authors reported insufficient information to enable a judgement, and we documented the reasons for the judgement made. We have summarized the criteria we used in Appendix 3.
Statistical analysis and data synthesis

The comparisons made in this review can be considered in a hierarchy. We classified the data on each test type in the primary studies according to commercial brands. In order to provide a coherent description of the studies contributing to each analysis, we structured the results first by grouping studies according to their commercial brand, then grouping brands to form test types. The analytical strategy thus compared the test accuracy of commercial brands within each test type before making comparisons between test types. Comparative analyses first included all studies with relevant data, and were then restricted to studies that made direct comparisons between tests with the same participants, where such studies existed.

For each test type, we plotted estimates of the observed sensitivities and specificities in forest plots and in receiver-operating characteristic (ROC) space. These plots illustrate variation in accuracy between studies. Where adequate data were available, we performed meta-analyses using the bivariate model (Reitsma 2005) to produce summary sensitivities and specificities. Using a random-effects approach, the model jointly synthesises sensitivity and specificity by allowing for correlation between them across studies. We made comparisons between tests by adding a covariate for brand or test type to the bivariate model to investigate association with sensitivity or specificity, or both. Also, we investigated the effect of test type on the variances of the random effects of logit sensitivity and logit specificity and we included separate variance terms where required. We assessed the significance of the difference in test performance by a likelihood ratio test comparing models with and without covariate terms for sensitivity and specificity. Where inadequate studies were available to estimate all parameters, we simplified the bivariate model to two univariate random-effects logistic regression models by assuming no correlation between sensitivity and specificity. We fitted the models using the xtmelogit command in StataCorp 2011.

Where more than one commercial brand of the same test type was evaluated on the same patients against the same reference standard, we selected one brand at random from the analysis by test type in order to avoid bias due to inclusion of the same participants more than once in the analysis. We included both brands in any analyses comparing commercial brands.

Investigations of heterogeneity

We inspected forest plots and summary ROC plots to visually assess heterogeneity between study specific estimates of sensitivity and specificity. We planned to investigate the effect of age group, continent where the study took place, and adequacy of the reference standard on summary estimates of sensitivity and specificity by adding each factor as a covariate to the bivariate model. We did not attempt to assess reporting bias because little is known about how this should be done for diagnostic test accuracy (DTA) reviews.

Results of the search

In the initial search we identified 4837 titles, of which we excluded 4325 based on their title or abstract alone. We were unable to obtain one article in full text form. We retrieved full text articles for 511 titles; of which we excluded 474 articles; 316 because they were initially assessed as ineligible; 22 because the reports did not present enough information for us to assess their eligibility; 21 because they were available only in non-English languages; 21 because we were unable to extract absolute numbers of true positives, false positives, false negatives and true negatives; and 94 because they did not present data on non-falciparum or Plasmodium vivax malaria, although they were eligible for other reviews in this series. See Figure 1 for a flow diagram of search and eligibility results.
Figure 1. Study flow diagram.

4827 records identified through database searching

0 additional records identified through other sources

4827 of records after duplicates removed

4837 records screened

4324 records excluded

512 full-text articles assessed for eligibility

475 full-text articles excluded, with reasons

37 studies included in qualitative synthesis

37 studies included in quantitative synthesis (meta-analysis)
We therefore included a total of 37 study publications. One of the included publications described two related studies, and another publication reported data separately for 10 different sites, making a total of 47 study cohorts. Seven of the 47 cohorts evaluated more than one test; one compared four tests, three compared three tests and three compared two tests. There were a total of 67 test evaluations reporting on a total of 32,466 tests in 22,862 participants.

We have given a summary of the number of studies by test type and reference standard (microscopy or PCR) in Table 3.

**Methodological quality of included studies**

We summarised the overall methodological quality of the included studies in Figure 2. Twenty-seven study cohorts (57%) clearly included a representative spectrum of patients attending ambulatory healthcare setting with symptoms of malaria; the remaining 20 were unclear, most often because they had not adequately described their sampling methods. Twenty study cohorts (43%) reported an adequate reference standard, 19 (40%) did not provide enough information on the reference standard, and eight (17%) had an inadequate reference standard, in all cases because a second microscopist did not verify the results. Thirty-five study cohorts (75%) reported blinding of the reference standard results, 11 (23%) did not describe whether the reference standard was blinded and one (2%) did not blind the reference standard. Thirty-seven (79%) study cohorts blinded the RDT results to the results of the reference tests, nine (19%) were unclear and one (2%) did not blind the RDTs. All 47 cohorts reported avoidance of partial verification, differential verification and incorporation.

![Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.](image)

Eleven study cohorts (23%) reported on uninterpretable test results; of these, three excluded uninterpretable results from the analysis, four reported that there were no uninterpretable results, three repeated any uninterpretable tests and one presented the results for uninterpretable tests. The proportion of uninterpretable tests was low in every study that reported this information (maximum 6%). Thirty study cohorts (64%) did not report on uninterpretable results, but appeared to have no uninterpretable results, because they had an exact correlation between the number of participants en-
rolled and the number presented in the analysis. Six study cohorts (13%) did not report on uninterpretable results and also either did not clearly state the number of participants initially enrolled or showed a discrepancy between the number of participants enrolled and the number presented in the analysis.

Thirty-seven study cohorts (79%) reported either no withdrawals from the study or recorded the reasons for any withdrawals; eight (17%) were unclear as to whether there were any withdrawals; one (2%) had one participant missing from the analysis, with no explanation, and another (2%) reported that samples with mixed infection or where microscopists disagreed were excluded, while the number of samples excluded, and the original number of participants enrolled, was not presented.

Findings

Target condition: non-falciparum malaria only

In this section we present the results for RDTs which identify 'non-falciparum malaria' by the presence of a positive pan-malaria antibody line in the absence of a positive *P. falciparum* specific antibody line.

Verified by microscopy

### Type 2 tests

There were 11 evaluations of Type 2 RDTs verified with microscopy (Figure 3); eight were undertaken in Asia, two in Africa and one in South America. The median sample size was 372 (range 113 to 2383), the median prevalence of non-falciparum only malaria was 14% (range 7% to 32%) and the median percentage of malaria that was non-falciparum was 46% (range 13% to 80%). None of the evaluations were undertaken only in children under the age of five years. Five different test brands were evaluated: ICT Malaria Pf/Pv (seven); ICT Malaria combo cassette (one), Malascan (one), NOW Malaria ICT (one) and VIKIA Malaria Ag Pf/Pan (one). Sensitivities of the tests ranged from 67% to 90%; specificities ranged from 89% to 100%. In meta-analysis (11 evaluations, 6879 participants) the pooled sensitivity was 78% (95% confidence interval (CI) 73% to 82%) and the specificity was 99% (95% CI 97% to 99%) (Figure 4). Of the false negative RDT results (where microscopy identified non-falciparum malaria only, but RDT gave a different result) 65% (95% CI 43% to 81%) of RDT results indicated 'no malaria'; the remaining false negative RDT results indicated *P. falciparum* or mixed infection (Table 4).

![Figure 3. Forest plot of commercial brands of Type 2 tests for detection of non-falciparum species (verified with microscopy). We ordered studies by continent, age group and study identifier.](image-url)
Figure 4. Summary ROC plot of Type 2 tests for detection of non-falciparum species (verified with microscopy). The black solid circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.
Type 3 tests

There were 25 evaluations of Type 3 RDTs verified with microscopy (Figure 5); eight were undertaken in Asia, 15 in Africa and two in South America. The median sample size was 200 (range 30 to 2585), the median prevalence of non-falciparum only malaria was 10% (range 7% to 36%) and the median percentage of malaria that was non-falciparum was 36% (range 17% to 85%). None of the evaluations were undertaken only in children under the age of five years. Five different test brands were evaluated: Parascreen (14), SD Malaria Antigen Bioline (four), Carestart Pf/Pan (four), First Response Malaria Combo (two) and One Step Malaria Pf/Pan (one). Sensitivities of the tests ranged from 25% to 100%; specificities ranged from 94% to 100%. Two studies evaluated two brands and so one brand was selected at random for inclusion in the meta-analysis. Therefore, based on 23 evaluations (11,234 participants), the pooled sensitivity was 78% (95% CI 69% to 84%) and the specificity was 99% (95% CI 98% to 99%) (Figure 6). Of the false negative RDT results (where microscopy identified non-falciparum malaria only, but RDT gave a different result), 74% (52% to 88%) of RDT results indicated ‘no malaria’; the remaining false negative RDT results indicated P. falciparum or mixed infection (Table 4).

Figure 5. Forest plot of commercial brands of Type 3 tests for detection of non-falciparum species (verified with microscopy). We ordered studies by continent, age group and study identifier.

| Study                  | TP  | FP  | FN  | TN  | Continent   | Age group   | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------------|-----|-----|-----|-----|-------------|-------------|----------------------|-----------------------|
| Achten 2011            | 293 | 86  | 43  | 2041| Africa       | Mixed ages  | 0.86 (0.77, 0.95)    | 0.86 (0.85, 0.88)    |
| Endeshaw 2012a         | 3   | 4   | 3   | 190 | Africa       | Mixed ages  | 0.66 (0.50, 0.83)    | 0.88 (0.80, 0.92)    |
| Endeshaw 2012b         | 32  | 4   | 4   | 160 | Africa       | Mixed ages  | 0.89 (0.84, 0.94)    | 0.98 (0.94, 0.99)    |
| Endeshaw 2012c         | 6   | 3   | 5   | 114 | Africa       | Mixed ages  | 0.65 (0.23, 0.83)    | 0.88 (0.85, 0.91)    |
| Endeshaw 2012d         | 2   | 1   | 2   | 195 | Africa       | Mixed ages  | 0.56 (0.37, 0.80)    | 0.98 (0.97, 1.00)    |
| Endeshaw 2012e         | 5   | 7   | 6   | 165 | Africa       | Mixed ages  | 1.00 (0.94, 1.00)    | 0.86 (0.83, 0.90)    |
| Endeshaw 2012f         | 8   | 0   | 6   | 192 | Africa       | Mixed ages  | 1.00 (0.83, 1.00)    | 0.80 (0.81, 1.00)    |
| Endeshaw 2012g         | 3   | 1   | 2   | 192 | Africa       | Mixed ages  | 0.66 (0.54, 0.85)    | 0.98 (0.97, 1.00)    |
| Endeshaw 2012h         | 14  | 0   | 2   | 194 | Africa       | Mixed ages  | 0.68 (0.52, 0.86)    | 1.00 (0.99, 1.00)    |
| Endeshaw 2012i         | 10  | 4   | 6   | 186 | Africa       | Mixed ages  | 1.00 (0.89, 1.00)    | 0.98 (0.95, 0.99)    |
| Endeshaw 2012j         | 11  | 3   | 11  | 101 | Africa       | Mixed ages  | 0.76 (0.47, 0.97)    | 0.98 (0.95, 1.00)    |
| Erlers 2013            | 44  | 6   | 13  | 303 | Asia         | Adults only | 0.77 (0.74, 0.92)    | 0.98 (0.96, 0.99)    |
| Erlers 2013            | 48  | 3   | 5   | 270 | Asia         | Mixed ages  | 0.61 (0.39, 0.97)    | 0.88 (0.87, 1.00)    |
| Benedetti 2010         | 84  | 8   | 15  | 243 | South America| Adults only | 0.77 (0.84, 0.95)    | 0.97 (0.95, 1.00)    |

| Study                  | TP  | FP  | FN  | TN  | Continent   | Age group   | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------------|-----|-----|-----|-----|-------------|-------------|----------------------|-----------------------|
| Achten 2011            | 209 | 77  | 37  | 2060| Africa      | Mixed ages  | 0.85 (0.81, 0.89)    | 0.96 (0.96, 0.97)    |
| Erlers 2013            | 3   | 4   | 2   | 704 | Asia        | Mixed ages  | 0.00 (0.00, 0.00)    | 0.00 (0.00, 1.00)    |
| Erlers 2013            | 20  | 4   | 30  | 195 | Africa      | Mixed ages  | 0.04 (0.02, 0.11)    | 0.00 (0.00, 0.00)    |
| Xibrit 2015            | 56  | 0   | 6   | 115 | Asia        | Mixed ages  | 0.01 (0.00, 0.02)    | 1.00 (0.87, 1.00)    |

| Study                  | TP  | FP  | FN  | TN  | Continent   | Age group   | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------------|-----|-----|-----|-----|-------------|-------------|----------------------|-----------------------|
| Rahvarahan 2007         | 11  | 4   | 4   | 175 | Africa      | Mixed ages  | 0.73 (0.45, 0.85)    | 0.00 (0.00, 0.00)    |
| Dev 2004               | 5   | 0   | 2   | 23  | Asia        | Mixed ages  | 0.27 (0.29, 0.34)    | 1.00 (0.66, 1.00)    |
| Poon 2013              | 404 | 26  | 133 | 1872| Asia        | Adults only | 0.72 (0.74, 0.79)    | 0.99 (0.98, 1.00)    |
| Treacy 2012            | 111 | 2   | 10  | 929 | South America| Mixed ages | 0.99 (0.98, 1.00)    | 0.99 (0.98, 1.00)    |

| Study                  | TP  | FP  | FN  | TN  | Continent   | Age group   | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------------|-----|-----|-----|-----|-------------|-------------|----------------------|-----------------------|
| Singh 2009             | 40  | 11  | 9   | 394 | Asia        | Adults only | 0.64 (0.52, 0.77)    | 0.97 (0.94, 0.99)    |
| Bhaskar 2008           | 34  | 15  | 7   | 235 | Asia        | Mixed ages  | 0.62 (0.58, 0.67)    | 0.89 (0.80, 0.98)    |

| Study                  | TP  | FP  | FN  | TN  | Continent   | Age group   | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------------|-----|-----|-----|-----|-------------|-------------|----------------------|-----------------------|
| Yan 2013               | 51  | 5   | 22  | 530 | Asia        | Mixed ages  | 0.79 (0.60, 0.93)    | 0.99 (0.95, 1.00)    |
Figure 6. Summary ROC plot of Type 3 tests for detection of non-falciparum species (verified with microscopy). The black solid circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.
Type 4 tests

There were 11 evaluations of Type 4 RDTs compared microscopy (Figure 7); six were undertaken in Asia, two in Africa and three in South America. The median sample size was 289 (range 80 to 896), the median prevalence of non-falciparum only malaria was 27% (range 8% to 33%) and the median percentage of malaria that was non-falciparum was 51% (range 21% to 100%). None of the evaluations were undertaken only in children under the age of five years. Three different test brands were evaluated: OptiMAL (six), OptiMAL-IT (four) and Carestart Malaria Pf/Pan (one). Sensitivities of the tests ranged from 63% to 100%; specificities ranged from 94% to 100%. One study evaluated two brands and so one brand was selected at random for inclusion in the meta-analysis. Based on 10 evaluations (3831 participants), the pooled sensitivity was 89% (95% CI 79% to 95%) and the specificity was 98% (95% CI 97% to 99%) (Figure 8). Of the false negative RDT results (where microscopy identified non-falciparum malaria only, but RDT gave a different result), 87% (79% to 92%) of RDT results indicated 'no malaria'; the remaining false negative RDT results indicated P. falciparum or mixed infection (Table 4).

Figure 7. Forest plot of commercial brands of Type 4 tests for detection of non-falciparum species (verified with microscopy). We ordered studies by continent, age group and study identifier.
Figure 8. Summary ROC plot of Type 4 tests for detection of non-falciparum species (verified with microscopy). The black circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.
Other test types
There was one evaluation of Malariagen Malaria, a type of test that does not fit into the classification presented in Table 1. Malariagen Malaria uses antibodies to the HRP-2 antigen of *P. falciparum* and unspecified monoclonal antibodies for detection of pan-malarial antigens. The study (Selimuzzaman 2010) was undertaken on a sample of 262 adults in Asia and the study prevalence of non-falciparum malaria was 5%. The sensitivity of this test verified against microscopy was 92% (95% CI 62% to 100%) and the specificity was 95% (95% CI 92% to 97%).

Comparisons between RDT types
We summarised the comparison of different RDT types in Figure 9, Figure 10, Table 5 and Table 6. There was a statistically significant (P = 0.008) difference in accuracy between test types (Table 5) with Type 4 tests being significantly more sensitive than Type 2 (P = 0.01) and Type 3 (P = 0.03) (Table 6) based on indirect comparisons using all available data. Specificities were similarly high across the three test types. Few studies directly compared tests and so meta-analyses restricted to direct comparisons were not possible. The results from the only study (van den Broek 2006) that directly compared a Type 2 test and a Type 4 test were consistent with the meta-analytic finding and also demonstrated a statistically significant difference (P < 0.001) in sensitivity (Appendix 4).
Figure 9. Forest plot of Type 2, Type 3 and Type 4 tests for detection of non-falciparum species (verified with microscopy). We ordered studies by continent, age group and study identifier.
Figure 10. Summary ROC plot comparing Type 2, Type 3 and Type 4 tests for detection of non-falciparum species (verified with microscopy). The solid circles correspond to the summary estimates of sensitivity and specificity for each test type, and are shown with 95% confidence regions (dotted lines) and 95% prediction regions (dashed lines). The summary points for Type 2 and Type 3 and their 95% confidence regions are identical but the 95% prediction regions differ. The 95% prediction regions illustrate the extent of between study heterogeneity.
Comparison of brands

We compared the test performance of three Type 3 test brands-Parascreen (14 studies, 547 participants), Carestart Pf/Pan (four studies, 3544 participants) and SD Malaria Antigen Bioline (four studies, 3769 participants). We excluded the other two brands-First Response Malaria Combo (two studies, 663 participants) and One Step Malaria Pf/Pan (one study, 606 participants)-from the analysis due to limited data. There was no evidence (P = 0.88) to suggest that the sensitivity or specificity, or both, of type 3 tests was associated with brand. The summary sensitivity (95% CI) was 79% (67% to 88%) for Parascreen, 74% (45% to 91%) for Carestart Pf/Pan, and 80% (73% to 85%) for SD Malaria Antigen Bioline. The summary specificity (95% CI) was 98% (98% to 99%) for Parascreen, 99% (96% to 100%) for Carestart Pf/Pan, and 99% (98% to 100%) for SD Malaria Antigen Bioline.

For Type 4 tests, we compared the diagnostic accuracy of the OptiMAL (six studies, 1843 participants) and OptiMAL-IT (four studies, 1987 participants) brands. We excluded a third brand, Carestart Pf/Pan (one study, 195 participants), because of limited data. There was no evidence (P = 0.79) to suggest a difference in the sensitivity or specificity, or both, of the two brands. The summary sensitivity of OptiMAL was 90% (85% to 93%) and that of OptiMAL-IT was 91% (49% to 99%). The summary specificities were 98% (97% to 99%) and 98% (96% to 99%) for OptiMAL and OptiMAL-IT respectively.

Investigations of heterogeneity

Due to the limited number of studies available for each test type, we were only able to investigate the effect of continent and adequacy of the reference standard on the sensitivity and specificity of Type 3 tests for detecting non-falciparum species with microscopy as reference standard. There were three continents-Africa (14 studies, 5551 participants), Asia (eight studies, 4997 participants) and South America (two studies, 704 participants)-but we excluded South America from the analysis due to the limited data available. There was no evidence (P = 0.55) to suggest a difference in sensitivity or specificity, or both, between studies conducted in Africa and those in Asia. The summary sensitivity (95% CI) was 74% (57% to 86%) for Africa and 80% (73% to 85%) for Asia. The summary specificity (95% CI) was 99% (98% to 99%) for Africa and 99% (97% to 99%) for Asia. For adequacy of the reference standard, six studies were scored ‘Yes’, 12 studies were scored ‘No’ and five studies were scored ‘Unclear’; there was no evidence (P = 0.54) to suggest a difference in sensitivity or specificity, or both. The summary sensitivity and specificity were 77% (67% to 85%) and 99% (98% to 99%) for studies with an acceptable reference standard; 78% (65% to 88%) and 99% (98% to 99%) for studies without an acceptable reference standard; and 86% (78% to 91%) and 98% (97% to 99%) for studies where the assessment was judged to be unclear.

Verified by PCR

Type 2 tests

No study verified a Type 2 test with PCR.

Type 3 tests

There were five evaluations of a Type 3 test verified with PCR (Figure 11); three were undertaken in Asia and two were undertaken in South America. The median sample size was 327 (range 178 to 606), and the median prevalence of non-falciparum malaria was 15% (range 7% to 33%). None of the evaluations were undertaken only in children under the age of five years. Four different test brands were evaluated; Parascreen (two studies); SD Malaria Antigen Bioline (one study), CareStart Pf/Pan (one study) and One Step Malaria Pf/Pan (one study). Sensitivities of the tests ranged from 64% to 91% and specificities ranged from 97% to 100%. In meta-analysis, the pooled sensitivity was 81% (95% CI 72% to 88%) and the pooled specificity was 99% (95% CI 97% to 99%).
Figure 11. Summary ROC plot of Type 3 tests for detection of non-falciparum species (verified with PCR). The solid circles correspond to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.
Type 4 tests

One study (Rakotonirina 2008) verified a Type 4 test, OptiMAL, against PCR and gave results consistent with the summary results of the six studies that used microscopy as the reference standard (Appendix 5).

Comparison of results verified by microscopy or PCR

Four studies used both microscopy and PCR as reference standards to verify parasitaemia. Elahi 2013 estimated a sensitivity of 91% and specificity of 99% for both PCR and microscopy; Bendezu 2010 estimated a sensitivity of 76% and specificity of 98% with PCR, and sensitivity of 77% and specificity of 99% with microscopy. The accuracy of CareStart Pf/Pan reported by Xiao Dong 2013 was similar for both reference standards with sensitivity of 91% and specificity of 100%. Yan 2013 evaluated One Step Malaria Pf/Pan with an estimated sensitivity of 72% when verified against PCR and 70% against microscopy, and a specificity of 97% with PCR and 99% with microscopy. Ratimbaso 2008 verified the Malaria Antigen Bioline test against PCR and gave results within the 95% CI of the pooled results of the two studies that used microscopy as the reference standard (Appendix 5).

Target condition: P. vivax

In this section we present the results for RDTs which identify P. vivax by the presence of a positive P. vivax specific antibody line. The majority of the tests had two test lines, an HRP-2 line to detect P. falciparum and an pLDH line to detect P. vivax. One study, which verified results using PCR, evaluated a Type 6 tests, with additional test with an additional pan line to detect all species of malaria. In each case, only the Pv pLDH line is considered in the analysis.

Verified by microscopy

Eight studies evaluated the performance of Pf HRP-2 and Pv pLDH antibody tests verified with microscopy-four were undertaken in Africa and four in Asia (Figure 12). The median sample size was 361 (range 240 to 1092), with a median prevalence of P. vivax malaria of 19% (range 2% to 45%). Evaluations were conducted in mixed age groups or adults only. Five different test brands were assessed: CareStart Pf/Pv (three), Falcivax (two), Biotech Malaria Pf/Pv (one), OnSite Pf/Pv (one), and Pf/Pv Malaria Device (one). The sensitivities of the tests ranged from 66% to 100%, and specificities ranged from 98% to 100%. In meta-analysis (eight evaluations, 3682 participants) the summary sensitivity and specificity (95% CI) were 95% (86% to 99%) and 99% (99% to 100%) respectively (Figure 13).

Figure 12. Forest plot of Pf HRP-2 and Pv pLDH for detection of P. vivax (verified with microscopy). Studies are ordered by continent, age group and study identifier.
Figure 13. Summary ROC plot Pf HRP-2 and Pv pLDH for detection of P. vivax (verified with microscopy). The black circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.
Two studies evaluated the performance of three different brands of Pf HRP-2 and Pv pLDH antibody tests against PCR. One study was undertaken in Bangladesh and the other in China. Sensitivities ranged from 59% (47% to 70%) to 77% (56% to 91%) and specificities ranged from 97% (95% to 99%) to 100% (99% to 100%). One study evaluated a Type 6 RDT and reported a sensitivity of 90% (70% to 99%) and specificity of 100% (99% to 100%).

Additional analyses

Sensitivities of tests at different levels of \( P. \) vivax parasitaemia

**Type 2 tests**

Four studies presented additional data relating to the sensitivity of Type 2 RDTs against microscopy at different levels of parasitaemia (Fernando 2004; Tjitra 1999; van den Broek 2006; Wongsrichanalai 2003). The findings varied; all found very low sensitivities below 100 parasites per µL, rising with level of parasitaemia, but the level at which a high sensitivity (over 90%) was achieved varied between 500 parasites per µL and 5,000 parasites per µL.

**Type 3 tests**

Four studies presented additional data relating to the sensitivity of a Type 3 RDT against microscopy at different levels of parasitaemia. In Ratsimbasoa 2008 sensitivity was 93% at levels of 501 to 5000 asexual parasites per µL; and 100% at levels above 5000 asexual parasites per µL. In Mohon 2012, sensitivity ranged from 80% at 1 to 100 asexual parasites per µL, to 90% at 101 to 500 asexual parasites per µL to 100% at 501 or more asexual parasites per µL. In Yan 2013, sensitivity was 73.3% at under 500 asexual parasites per µL to 100%, and 69% at over 5000 asexual parasites per µL to 100%. In Kosack 2013 sensitivity was 14% at one to 10 asexual parasites per 100 fields, 70% at one to 10 asexual parasites in 10 fields, 96% at one to 10 asexual parasites per field, and 98% at more than 10 asexual parasites per field.

**Type 4 tests**

Three studies presented additional data relating to the sensitivity of Type 4 RDTs against microscopy at different levels of parasitaemia, although two had only small numbers. One study presented useful data (Valecha 2003), reporting a sensitivity of 30% at under 500 asexual parasites per µL; 48% at 500 to 999 asexual parasites per µL; 91% at 1000 to 5000 asexual parasites per µL; and 100% at over 5000 asexual parasites per µL.
## Summary of findings

| Patients/populations | People presenting with symptoms suggestive of uncomplicated malaria |
|----------------------|---------------------------------------------------------------|
| Prior testing        | None                                                           |
| Settings             | Ambulatory healthcare settings in *P. vivax*, *P. malariae* or *P. ovale* malaria endemic areas in Asia, Africa and South America |
| Index tests          | Immunochromatography-based rapid diagnostic tests (RDTs) for non-falciparum malaria in the absence of *P. falciparum* co-infection, or *P. vivax* malaria with or without other malaria species |
| Reference standard   | Conventional microscopy, polymerase chain reaction (PCR) |
| **Importance**       | Accurate and fast diagnosis allows appropriate and quick treatment for malaria to be provided |
| Studies              | 37 unique publications reporting 47 studies (22,862 participants) |
| Quality concerns     | Poor reporting of patient characteristics, sampling method and reference standard methods were common concerns |

### Quantity of evidence

| Test type | Quantity of evidence | Average sensitivity (95% CI) | Average specificity (95% CI) | Prevalence (%) | Consequences in a cohort of 1000 |
|-----------|----------------------|------------------------------|------------------------------|----------------|----------------------------------|
|           | Number of evaluations (malaria cases/participants) |                              |                              |                | Missed cases | False positives |
| **Type 2** |                  |                              |                              |                |                   |
| HRP-2 (*P. falciparum* specific) and aldolase (pan-specific) | 11 (743/6879) | 78% (73% to 82%) | 99% (97% to 99%) | 5 | 11 | 10 |
|           |                  |                              |                              | 15 | 33 | 9 |
|           |                  |                              |                              | 30 | 66 | 7 |
| **Type 3** |                  |                              |                              |                |                   |
| HRP-2 (*P. falciparum* specific) and pLDH (pan-specific) | 23 (1537/11,234) | 78% (69% to 84%) | 99% (98% to 99%) | 5 | 11 | 10 |
|           |                  |                              |                              | 15 | 33 | 9 |
|           |                  |                              |                              | 30 | 66 | 7 |
### Type 4
- pLDH (*P. falciparum* specific) and pLDH (pan-specific)

|                | Target condition (reference standard): non-falciparum malaria (PCR) | Target condition (reference standard): *P. vivax* with or without other malaria species (microscopy) |
|----------------|---------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|
| **Type 3**     | 10 (846/3831) 89% (79% to 95%) 98% (97% to 99%) 5 6 19 | 8 (531/3682) 95% (86% to 99%) 99% (99% to 100%) 5 3 10 |
| HRP-2          | 5 (240/1639) 81% (72% to 88%) 99% (97% to 99%) 5 10 10 | 8 (313/3682) 95% (86% to 99%) 99% (99% to 100%) 5 8 9 |

**Conclusions:** The majority of studies evaluated RDTs which are designed to differentiate falciparum malaria from non-falciparum malaria, but cannot differentiate between different non-falciparum species or identify non-falciparum malaria species within a mixed infection. In these types of tests, specificity for non-falciparum malaria in the absence of *P. falciparum* infection was high, but sensitivity was low, tests missing between 11% and 22% of non-falciparum cases. RDTs which are designed to detect *P. vivax* specifically, whether alone or part of a mixed infection, were more accurate with tests missing less than 5% of *P. vivax* cases. This review can help decision-making about which RDT to use, in combination with other published information about in vitro test performance and stability in the field.
**Discussion**

**Summary of main results**

Test Types 2, 3 and 4, and other tests that identified non-falciparum malaria through deduction of a positive result for pan-malarial antigens along with a negative result for *P. falciparum* specific antigens, had sensitivities that ranged in pooled analyses from 78% (Type 2) to 89% (Type 4). Further analysis of the false negative results showed that the majority of non-falciparum only cases that were missed by the RDTs were indicated as 'no malaria' although some were indicated as *P. falciparum* or mixed infection. Type 4 tests were significantly more sensitive than Type 2 tests. Specificities were consistently high, ranging from 98% (Type 4) to 99% (Type 2 and Type 3). There were no apparent differences between microscopy and PCR as the reference standard.

In studies that verified RDTs with microscopy, tests that used a *P. vivax* specific antibody line to identify *P. vivax* had a pooled sensitivity of 95% (95% CI 86% to 99%) and a pooled specificity of 99% (95% CI 99% to 100%). In contrast, the two studies that verified these types of RDTs with PCR demonstrated much lower sensitivity of 59% (47% to 70%) and 77% (56% to 91%).

In **Summary of findings**, assuming prevalences of 5%, 15% and 30%, the number of missed non-falciparum or *P. vivax* malaria cases and the number of false positives in a hypothetical cohort of 1000 patients are presented by test type. In the case of tests for non-falciparum only, the performance may in reality be affected by the prevalence of *P. falciparum* parasitaemia; this effect is not possible to estimate with any accuracy, however it is likely to be small, and has therefore been ignored.

**Strengths and weaknesses of the review**

**Completeness of evidence**

It is probable that some studies eligible for inclusion in the review were missed by our search strategy. DTA studies are known to be poorly indexed, and hence liable to be missed, even when searches are designed to be very sensitive (Whiting 2009). However, our search was comprehensive.

**Accuracy of the reference standards used**

Microscopy is an imperfect diagnostic test in itself, raising the possibility that in some cases of discordant results between microscopy and RDT, the RDT result may in fact have been correct, and the microscopy results incorrect. However, with the exception of *P. vivax* specific tests, where only two studies verified by PCR were available, results for studies which verified RDT results against PCR gave similar results to those which used microscopy as a reference standard.

In studies reporting on sensitivity by parasitaemia level, RDTs tended to reach high levels of sensitivity (above 90%) at levels of parasitaemia above 500 to 1000 asexual parasites for *P. vivax*, but were less reliable at lower levels. This finding corresponds closely with a similar analysis within a DTA review of RDTs for travellers with fever returning from malaria endemic to non-endemic areas (Marx 2005).

**Quality of reporting of the included studies**

The quality of reporting of the included studies, as assessed by the number of 'unclear' evaluations of study quality was variable. Nineteen study cohorts (40%) did not provide enough information for us to adequately assess the adequacy of the reference standard, which we judged to be the most important quality indicator for this review.

**Quality of the included studies**

Where sufficient information was provided to assess the quality of included studies, the quality was variable. Twenty (43%) study cohorts reported an adequate reference standard, while 37 (79%) reported that readers of the reference standard were blinded to the results of the RDTs. For Type 3 tests, we were able to investigate the effect of adequacy of the reference standard on test performance. There was no evidence of a difference in test performance between studies with an adequate, inadequate or unclear reference standard.

**Completeness and relevance of the review**

This review focused specifically on the use of RDTs for diagnosing non-falciparum malaria in people living in malaria endemic areas and attending ambulatory health care setting with symptoms of malaria; therefore evaluating the tests in the context in which they are intended to be most often used. Previously published reviews have evaluated the accuracy of RDTs under laboratory conditions (WHO 2012) and for use by travellers returning from malaria endemic to non-endemic areas (Marx 2005). By classifying asexual parasitaemia as positive and gametocytes only as negative we focused on malarial illness requiring curative treatment, in line with current treatment recommendations (WHO 2010). In the future, as malaria comes closer to elimination, it may become important to cure gametocytaemia to prevent transmission, and diagnostic priorities may change.

**Applicability of findings to the review question**

**Qualities of RDTs**

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)
RDT types 2, 3 and 4, which aim to identify ‘non-falciparum malaria only’ as a proxy for *P. vivax* may miss between 11% (Type 4) and 22% (Type 2 and Type 3) of cases, with the majority of missed cases being incorrectly identified as free of malaria. In addition, the design of these tests does not allow the identification of non-falciparum malaria as part of a mixed infection, or the differentiation of *P. vivax* from *P. ovale* and *P. malariae*. These tests therefore do not appear adequately sensitive for the identification of *P. vivax*, although they may play a role in areas where both *P. vivax* and *P. falciparum* occur and are initially treated with the same drugs. In contrast, RDT types using pLDH designed to detect *P. vivax* specifically, whether alone or part of a mixed infection appear to be both highly sensitive (missing 5% of cases) and highly specific for *P. vivax*. However, two studies included in this review, which verified the test with PCR, found much lower sensitivities. Consideration also needs to be made for variation in sensitivity by brand (WHO 2012).

**Application to clinical decision-making in practice**

The evaluations presented in this review were conducted in patients with symptoms of clinical malaria and inferences about the results relate to this context, and not to mass surveys of well populations. The evaluations should also be read in conjunction with other published information regarding the in vitro performance, stability and costs of the tests, including the WHO FIND report (WHO 2012). Results between this review and the FIND analysis for some RDTs differ slightly. The FIND report tested individual products under laboratory conditions using standardised blood samples at low and high parasite densities (200 and 2000 parasites per µL) and reported the ‘panel detection score’; which is defined as the percentage of times that two tests within a batch detected parasites at low density, and percentage of times that one test detected parasites at high density. This measure is slightly different to sensitivity, as it includes an aspect of consistency, whereas the studies in this review were conducted in field conditions with patients, and this is likely to account for variations between the datasets. The results in our review more closely mimic the conditions in which the tests would be used in practice; where parasite density is generally unknown, and may be affected by storage of the test, quality of a specific batch, local parasite densities, local parasite antigen patterns, quality of local microscopy and accuracy of reading the tests. Equally, these factors bring in more variation than tests from a laboratory using standardised samples. RDTs can only influence clinical practice if the results are believed and acted upon. There may be reluctance on the part of both health providers and patients to believe negative RDT results, leading to unnecessary repeat testing and prescription of antimalarials for negative cases (Tavrow 2000).

Various studies have shown that patients with fever and negative malaria test results, whether by microscopy or RDT, often still receive antimalarials (Hamer 2007), thus reducing their potential usefulness and cost-effectiveness. However, some educational interventions have been shown to be effective in reducing prescriptions for antimalarials in negative cases (Ngasala 2008).

**Authors’ conclusions**

**Implications for practice**

RDT types 2, 3 and 4, which aim to identify ‘non-falciparum malaria only’ as a proxy for *P. vivax* are limited by their design as they are unable to identify *P. vivax* specifically or to identify any species of non-falciparum malaria as part of mixed infection. In addition, they have a relatively low sensitivity for ‘non-falciparum malaria only’. They may be useful in areas where the majority of malaria is caused by *P. falciparum* or mixed infection and where good quality microscopy is not available; our related review (Abba 2011) has shown that these test types are sensitive for the detection of *P. falciparum*. RDT types which are designed to detect *P. vivax* specifically, whether alone or part of a mixed infection appear to be both more directly applicable to practice in *P. vivax* endemic areas and in the majority of published studies have been shown to be more accurate. Data were insufficient to determine test accuracy by parasite density, which will affect the sensitivity and specificity thresholds that decide whether a test is useful in practice.

**Implications for research**

More studies are needed to assess the accuracy of the newer RDT types designed to detect *P. vivax* specifically, particularly in areas with low prevalence.

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Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or Plasmodium vivax malaria in endemic countries (Review)

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Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or Plasmodium vivax malaria in endemic countries (Review)

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* Indicates the major publication for the study
# Characteristics of included studies  
**Alam 2011**

| Clinical features and settings | Presenting signs and symptoms: Fever  
Previous treatments for malaria: No explicit exclusions based on previous treatment and no information presented on previous treatment  
Clinical setting: Matiranga Upazila Health Complex (UHC)  
Country: Bangladesh  
Malaria endemicity: Perennial transmission of malaria with 2 peaks in pre-monsoon (March-May) and post-monsoon (September to November) periods  
Malaria endemic species: *P. falciparum* and *P. vivax* |
|---|---|
| Participants | Sample size: 338  
Age: Median age was 14 years and the range was 18 months to 82 years  
Sex: Both males and females eligible. 50.3% of participants were female  
Co-morbidities or pregnancy: Not mentioned, either as an inclusion criteria or characteristic of included participants |
| Study design | Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 4 RDTs: Paracheck test was performed at concurrently with the microscopy. The remaining 3 RDTs were performed using stored samples. Samples from each individual were tested by all tests |
| Target condition and reference standard(s) | Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*  
Reference standard test(s) used: Microscopy, thick and thin smear slides and PCR  
Who performed the reference standard tests, and where? 2 independent microscopists: 1 employed by the study and the other at Matiranga UHC; not reported for PCR  
If microscopy was used, how many high power fields were looked at? 200 fields in the Giemsa-stained thick film  
How many observers or repeats were used? 2 observers  
How were discrepancies between observers resolved? By a third microscopist posted at the Khagrachari Civil Surgeon’s office situated 20 km away from Matiranga UHC |
| Index and comparator tests | Commercial name of the test: Paracheck (Orchid Biomedical System, India), FalciVax Pf (Zephyr Biomedicals, India), Onsite Pf (CTK Biotech Inc, USA) and Onsite Pf/Pv (CTK Biotech Inc, USA)  
Parasite species the test is designed to detect:  
- Paracheck: *P. falciparum*  
- Onsite Pf: *P. falciparum*  
- FalciVax: *P. vivax* and *P. falciparum*  
- Onsite Pf/Pv: *P. vivax* and *P. falciparum*  
Designated type:  
- Paracheck: Type 1  
- Onsite Pf: Type 1  
- FalciVax: Type Other (HRP-2 antigen for *P. falciparum* and pLDH antigen for *P. vivax*)  
- Onsite Pf/Pv: Type Other (HRP-2 antigen for *P. falciparum* and pLDH antigen}
for P. vivax)

**Batch numbers:** Not provided

**Transport and storage conditions:** Not provided

**Who performed the index test, and where?** Not reported. All the RDTs were used following the manufacturer's instructions

### Follow-up

### Notes

**Source of funding:** funded by icddr,b and its donors. Paracheck provided by NMCP; Onsite Pf and Onsite Pf/Pv provided by CTK Biotech Inc, USA as a donation

### Table of Methodological Quality

| Item                                     | Authors' judgement | Description                                                                                                                                 |
|------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum? All tests       | Unclear            | Febrile patients referred to microscopy for malaria diagnosis. Other characteristics, inclusion and exclusion criteria not described             |
| Acceptable reference standard? All tests | Yes                | Microscopy: 2 experienced, independent microscopists assessed each slide. There was provision for a third microscopist to resolve any disagreement between them. 200 fields were viewed, another 200 fields were viewed if malaria was identified, to identify mixed infections PCR is also a reference standard. |
| Partial verification avoided? All tests  | Yes                | All participants receiving index tests had their diagnosis verified by reference test                                                        |
| Differential verification avoided? All tests | Yes                | The same reference tests were used regardless of the index test results                                                                      |
| Incorporation avoided? All tests         | Yes                | The reference standard was microscopy and PCR.                                                                                                                                                   |
| Reference standard results blinded? All tests | Unclear            | Blinding not described.                                                                                                                      |
| Index test results blinded? All tests    | Unclear            | Blinding not described.                                                                                                                      |
| Uninterpretable results reported? All tests | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |

Alam 2011  (Continued)
### Alam 2011 (Continued)

| Withdrawals explained? | All tests | The number recruited into the study was clearly stated and corresponded with the number included in the analysis, therefore there were no withdrawals |
|------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------|

### Andrade 2010

| Clinical features and settings | Presenting signs and symptoms: Malaria-related symptoms Previouis treatments for malaria: Not mentioned, either as an inclusion criteria or characteristic of included participants Clinical setting: Diagnostic centres of the Brazilian National Foundation of Health (FUNASA) Country: Brazil Malaria endemicity: Not stated Malaria endemic species: *P. falciparum* and *P. vivax* |
|---------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|
| Participants        | Sample size: 311 Age: Median age was 33.5 years and the range was 4 to 65 years Sex: Both males and females eligible. 60.5% of participants were male Co-morbidities or pregnancy: Not mentioned, either as an inclusion criteria or characteristic of included participants |
| Study design        | Participants were recruited consecutively. The sampling method was not described. 1 RDT was evaluated |
| Target condition and reference standard(s) | Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax* malaria Reference standard test(s) used: Microscopy thick and thin blood films and nested PCR Who performed the reference standard tests, and where? Experienced malaria field microscopists from the FUNASA performed microscopy; not stated who performed the nested PCR. All tests were repeated and confirmed at the main laboratory at the Centro de Pesquisas Goncalo Moniz, Bahia, Brazil If microscopy was used, how many high power fields were looked at? Not stated How many observers or repeats were used? 2 repeats with 2 different observers How were discrepancies between observers resolved? Not stated |
| Index and comparator tests | Commercial name of the test: Optimal-IT RDT (DiaMed China Ltd, Hong Kong, China) Parasite species the test is designed to detect: *P. falciparum* and *P. vivax* malaria Designated type: Antigens test detects stated Batch numbers: Not stated Transport and storage conditions: Not stated Who performed the index test, and where? Not stated |
| Follow-up           | Not applicable |
| Notes               | Source of funding: FINEP (010409605)/FNDCT-CT Amazônia. |
| Item                                | Authors' judgement | Description                                                                                                                                                                                                 |
|------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?           | Yes                | Patients were attending a clinic with symptoms of malaria. Study authors excluded people who had lived in the area for less than 6 months or had received antimalarials in the last 2 weeks |
| Acceptable reference standard?     | Unclear            | 2 independent microscopists performed microscopy, 1 in the field and 1 in the central laboratory. The number of fields viewed is not stated                                                                     |
| Partial verification avoided?      | Yes                | All participants who received the index test also received the reference tests                                                                                                                                |
| Differential verification avoided? | Yes                | The same reference tests were used regardless of the index test results                                                                                                                                     |
| Incorporation avoided?             | Yes                | The index test does not form part of the reference standard.                                                                                                                                                 |
| Reference standard results blinded?| Unclear            | Not reported whether the tests were read blindly.                                                                                                                                                            |
| Index test results blinded?        | Unclear            | Not reported whether the tests were read blindly.                                                                                                                                                            |
| Uninterpretable results reported?  | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results                                              |
| Withdrawals explained?             | Yes                | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results                                             |
### Clinical features and settings

**Presenting signs and symptoms:** Symptoms of uncomplicated malaria (axillary temperature > 37.5°C or report of fever in the previous 48 hours)

**Previous treatments for malaria:** Not mentioned, either as an inclusion criteria or characteristic of included participants

**Clinical setting:** 1 health centre and 3 health posts per woreda

**Country:** Ethiopia

**Malaria endemicity:** Not stated

**Malaria endemic species:** *P. falciparum* and *P. vivax*

### Participants

**Sample size:** 2400

**Age:** All ages over 6 months eligible. Actual age profile of participant population not presented

**Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated

**Co-morbidities or pregnancy:** Patients with any life-threatening diseases were excluded. No exclusion criteria based on pregnancy. No details about the frequency of pregnancy in the patient population are presented

### Study design

Enrolment was consecutive and prospective. 3 RDTs were evaluated (CareStart®, ParaScreen® and ICT Combo®). Each individual received all the tests

### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax* malaria

**Reference standard test(s) used:** Microscopy thick and thin blood films

**Who performed the reference standard tests, and where?** Staff at the health centre and experienced microscopists at a regional malaria reference laboratory who was blinded to the initial results. And a third, blinded, reading was conducted to address discrepancies

**If microscopy was used, how many high power fields were looked at?** 200 fields at 1000× magnification

**How many observers or repeats were used?** 2

**How were discrepancies between observers resolved?** They were corrected according to a third, blinded, readings: presence or absence of asexual parasites, difference in species, or > 50% difference in parasite count. Microscopy results and parasite counts were corrected according to the third reading

### Index and comparator tests

**Commercial name of the test:**
- CareStart® pf-HRP2/pan-pLDH (AccessBio, USA, catalogue number G0131SK)
- ParaScreen® pf-HRP2/pan-pLDH (Zephyr Biomedicals, India, catalogue number 50310025)
- ICT Combo® pf-HRP2/pan-aldolase (ICT Diagnostics, South Africa, catalogue number ML02)

**Parasite species the test is designed to detect:** Multi-species

**Designated type:**
- CareStart and ParaScreen - Type 3
- ICT Combo - Type 2

**Batch numbers:** Not stated

**Transport and storage conditions:**

"RDTs were transported unrefrigerated by air to Addis Ababa, where they were stored at ambient conditions until transfer to field sites. Temperature was monitored (Tinytag, Gemini Data Loggers, UK) but not controlled while RDTs were transported by road to"
health centres and during storage at the health centres. Temperatures during transport reached a maximum 36°C, but at health facilities temperatures did not exceed 30°C.

**Who performed the index test, and where?** Health extension workers or nurses at the health centres

| Follow-up | Not applicable |
| Notes | Source of funding: “United States Agency for International Development (Cooperative Agreement 663-A-00-09-00404-00). BC is funded by the ACT Consortium which is supported by a grant from the Bill & Melinda Gates Foundation to the London School of Hygiene and Tropical Medicine. Manufacturers supplied CareStart and ParaScreen RDTs free of charge for this evaluation, and ICT Combo was provided at a reduced price.” |

**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
| --- | --- | --- |
| Representative spectrum? All tests | Yes | Participants were visiting an outpatient department of a health centre with symptoms suggestive of malaria |
| Acceptable reference standard? All tests | Yes | 2 independent microscopists viewed the slides, a third viewed any discrepancies; 200 fields were looked at |
| Partial verification avoided? All tests | Yes | All participants who received the index test also received the reference test |
| Differential verification avoided? All tests | Yes | The same reference tests were used regardless of the index test results |
| Incorporation avoided? All tests | Yes | The index test does not form part of the reference standards |
| Reference standard results blinded? All tests | Yes | “RDT and microscopy results were read by different staff at the health centre, each blinded to the results of the other diagnostic technique” |
| Index test results blinded? All tests | Yes | “RDT and microscopy results were read by different staff at the health centre, each blinded to the results of the other diagnostic technique” |
| Uninterpretable results reported? All tests | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
### Ashton 2010 (Continued)

| Withdrawals explained? | Yes | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals |
|------------------------|-----|----------------------------------------------------------------------------------------------------------------------------------|

### Bell 2001a

#### Clinical features and settings
- **Presenting signs and symptoms**: History of fever, headache, chills or rigors occurring within the preceding 3 days; or more distant history of fever or non-specific signs suggestive of malaria
- **Previous treatment for malaria**: Participants who had recently taken antimalarials were not excluded; 5% of participants reported prior antimalarial use
- **Clinical setting**: Village health workers in 5 barangaya (districts)
- **Country**: Philippines (Agusan del Sur Province in the northeast of the island of Mindanao)
- **Malaria endemicity**: Generally low perennial transmission, with pockets of high transmission
- **Malaria endemic species**: *P. falciparum* and *P. vivax*

#### Participants
- **Sample size**: 350
- **Age**: Eligible age range not stated. Mean age of the participants was 19.5 years
- **Sex**: Both males and females eligible. There were 171 male and 179 female participants
- **Co-morbidities and pregnancy**: Not mentioned, either an exclusion criteria or characteristic of included participants
- **Parasite density of microscopy positive cases**: Not presented

#### Study design
- Enrolment was prospective. The sampling method was not described. 1 RDT was evaluated

#### Target condition and reference standard(s)
- **Target condition**: Malaria parasitaemia
- **Reference standard**: Microscopy of thick and thin blood smears
- **Who performed the reference standard tests, and where?**: An experienced local microscopist for all slides; selected slides were also read by an experienced parasitologist. Microscopy was performed in a local laboratory and hospital laboratory in Australia
- **If microscopy was used, how many high power fields were looked at?**: 100
- **How many observers or repeats were used?**: 1, except in discordant cases where RDT and microscopy results differed, all cases RDT-positive for *P. vivax* and 20% of cases negative by slide and RDT, in which case a second reader was used
- **How were discrepancies between observers resolved?**: The second, off-site reading was taken as the correct 1

#### Index and comparator tests
- **Commercial name of RDT**: ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia)
- **Parasite(s) designed to detect**: *P. falciparum* or mixed infection, non-falciparum malaria species only
- **Designated type**: Type 4
- **Batch numbers**: Not stated
- **Transport and storage conditions**: Refrigerated until 2 weeks before use
- **Person(s) performing RDT**: Researchers
**RDT setting:** Study villages

| Item                      | Authors’ judgement | Description                                                                                                                                 |
|---------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Table of Methodological Quality |                    |                                                                                                                                            |
| Representative spectrum?  | Unclear            | All participants had approached village health workers with symptoms suggestive of malaria, but the sampling method was not described.    |
| All tests                 |                    |                                                                                                                                            |
| Acceptable reference standard? | Yes               | An experienced microscopist viewed at least 100 high powered fields and discordant results were re-examined.                                   |
| All tests                 |                    |                                                                                                                                            |
| Partial verification avoided? | Yes               | All participants who received the index test also received the reference test.                                                                |
| All tests                 |                    |                                                                                                                                            |
| Differential verification avoided? | Yes          | The same reference test was used regardless of the index test results.                                                                    |
| All tests                 |                    |                                                                                                                                            |
| Incorporation avoided?    | Yes                | The index test does not form part of the reference standard.                                                                                |
| All tests                 |                    |                                                                                                                                            |
| Reference standard results blinded? | Yes         | “slides were read by a local microscopist who was not aware of the results of the ICT tests”                                              |
| All tests                 |                    |                                                                                                                                            |
| Index test results blinded? | Yes               | RDTs were performed 2 to 4 weeks before microscopy.                                                                                           |
| All tests                 |                    |                                                                                                                                            |
| Uninterpretable results reported? | Yes          | The paper reported that there was 1 uninterpretable microscopy result.                                                                     |
| All tests                 |                    |                                                                                                                                            |
| Withdrawals explained?    | Unclear            | The number of participants originally enrolled in the study was not stated; therefore it is unclear whether there were any withdrawals.    |
| All tests                 |                    |                                                                                                                                            |
Bell 2001b

Clinical features and settings

**Presenting signs and symptoms:** History of fever, headache, child or rigors occurring within the preceding 3 days; or more distant history of fever or non-specific signs suggestive of malaria

**Previous treatment for malaria:** Patients treated with antimalarials during the 4 weeks preceding the test were excluded from the analysis

**Clinical setting:** Health centre in Visaya

**Country:** Philippines (Agusan del Sur Province in the northeast of the island of Mindanao)

**Malaria endemicity:** Generally low perennial transmission, with pockets of high transmission

**Malaria endemic species:** *P. falciparum* and *P. vivax*

Participants

**Sample size:** 113

**Age:** Eligible age range not stated. Mean age of the participants was 19.8 years

**Sex:** Both males and females eligible. There were 73 male and 40 female participants

**Co-morbidities and pregnancy:** Not mentioned, either as an exclusion criteria or characteristic of included participants

**Parasite density of microscopy positive cases:** Not presented

Study design

- **Enrolment:** Prospective. The sampling method was not described. 1 RDT was evaluated

Target condition and reference standard(s)

**Target condition:** Malaria parasitaemia

**Reference standard:** Microscopy of thick and thin blood smears

**Who performed the reference standard tests, and where?** Not stated.

**Setting:** Regional Health Units

**If microscopy was used, how many high power fields were looked at?** Not stated, but probably 100 as in the other trial reported together in the same paper

**How many observers or repeats were used?** Not stated

**How were discrepancies between observers resolved?** Not applicable

Index and comparator tests

**Commercial name of RDT:** ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia)

**Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only

**Designated type:** Type 4

**Batch numbers:** Not stated

**Transport and storage conditions:** Stored by barangay health workers at room temperature, averaging about 25°C for up to 6 months

**Person(s) performing RDT:** Barangay health workers

**RDT setting:** Health centre

Follow-up

- **Not applicable**

Notes

- **Source of funding:** The Australian National Health and Medical Research Council

Table of Methodological Quality

| Item | Authors’ judgement | Description |
|------|-------------------|-------------|

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| Test Type                                      | Method Description                                                                 | Comments                                                                 |
|-----------------------------------------------|------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| Representative spectrum?                      | All tests                                                                          | All participants were attending a health centre with history of fever, headache, child or rigors within the preceding 3 days; more distant history of fever or non-specific signs suggestive of malaria; but the sampling method was not described |
| Acceptable reference standard?                | All tests                                                                          | No details given of the microscopy process.                               |
| Partial verification avoided?                 | All tests                                                                          | All participants who received the index test also received the reference test |
| Differential verification avoided?            | All tests                                                                          | The same reference test was used regardless of the index test results    |
| Incorporation avoided?                        | All tests                                                                          | The index test does not form part of the reference standard.              |
| Reference standard results blinded?           | All tests                                                                          | Clear that blinding had taken place, as it was not possible to match up all the RDT and microscopy results by name and date |
| Index test results blinded?                   | All tests                                                                          | Clear that blinding had taken place, as it was not possible to match up all the RDT and microscopy results by name and date |
| Uninterpretable results reported?            | All tests                                                                          | 25 of 393 tests done were considered invalid because of an indistinct control band. Invalid results were excluded from the analysis |
| Withdrawals explained?                       | All tests                                                                          | Only 113 microscopy results could be matched with RDT results by name and date; the others were lost from the analysis |
### Clinical features and settings

**Presenting signs and symptoms:** History of fever with or without chills, sweating and headache.

**Previous treatments for malaria:** No history of anti-malarial treatment during the last 2 weeks.

**Clinical setting:** Health facilities.

**Country:** Peru.

**Malaria endemicity:** "Despite a reduction of the incidence by up to 40% during the last 4 years in Peru, malaria due to *P. falciparum* and *P. vivax* remains an important public health problem, especially in the Amazon region where more than 70% of the cases of the country are reported."

**Malaria endemic species:** *P. falciparum* and *P. vivax*.

### Participants

**Sample size:** 332.

**Age:** Eligible age range not stated. Mean age was 32 ± 16 years.

**Sex:** Not mentioned either as an inclusion criteria or a characteristic of participants.

**Co-morbidities or pregnancy:** Not mentioned either as an inclusion criteria or a characteristic of participants.

### Study design

Enrolment was prospective. The sampling method was not described. 1 RDT was evaluated.

### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax* malaria.

**Reference standard test(s) used:** Microscopy thick and thin blood films and PCR.

**Who performed the reference standard tests, and where?** Reference standards were carried out by different staff blinded to each other result. Expert microscopy was carried out by experts in the 6 health centres; not described for PCR.

**If microscopy was used, how many high power fields were looked at?** Not stated.

**How many observers or repeats were used?** 10% of the slides were examined by a second expert microscopist at the reference laboratory.

**How were discrepancies between observers resolved?** Not stated.

### Index and comparator tests

**Commercial name of the test:** ParaScreen (Zephyr Biomedical Systems).

**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* species only.

**Designated type:** ParaScreen - Type 3.

**Batch numbers:** Lot 101051.

**Transport and storage conditions:** Not described.

**Who performed the index test, and where?** Not stated.

### Follow-up

### Notes

**Source of funding:** by The Global Fund to fight AIDS, Tuberculosis and Malaria through the - Organismo Andino de Salud - Convenio Hipolito Unanue' (Principal Recipient of the Multi-Country Malaria Project "Malaria control on the cross border areas of the Andean Region: A community based approach"-PAMAFRO), Grant Number MAA-305-G01-M; and by the Directorate General for Development Cooperation (DGCD) of the Belgian Government (framework agreement 02, 2003-2007), project 95501.
### Table of Methodological Quality

| Item                              | Authors’ judgement | Description                                                                                                                                                                                                 |
|-----------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?          | Yes                | Participants were attending health centres with fever and no history of malaria treatment within the last 2 weeks                                                                                             |
| Acceptable reference standard?    | No                 | Only 10% of slides were viewed twice. The number of high power fields viewed before declaring a sample negative was not stated                                                                                  |
| Partial verification avoided?     | Yes                | All participants who received the index test also received the reference test                                                                                                                                   |
| Differential verification avoided?| Yes                | The same reference tests were used regardless of the index test results                                                                                                                                       |
| Incorporation avoided?            | Yes                | The index test does not form part of the reference standard.                                                                                                                                                   |
| Reference standard results blinded?| Yes              | Reported that the tests were read blindly.                                                                                                                                                                   |
| Index test results blinded?       | Yes                | Reported that the tests were read blindly.                                                                                                                                                                   |
| Uninterpretable results reported? | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results                                           |
| Withdrawals explained?            | Yes                | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals                                                                 |

### Bharti 2008

**Clinical features and settings**

- **Presenting signs and symptoms:** Fever or history of fever, and suspicion of malaria
- **Previous treatment for malaria:** No exclusions based on previous treatment; it was undertaken in a remote area with no medical facilities
- **Clinical setting:** Mobile field clinics in ten villages
- **Country:** India (remote forested region of Jabalpur during the peak monsoon season)
- **Malaria endemicity:** Low endemic areas with higher transmission during the monsoon
- **Malaria endemic species:** *P. falciparum* and *P. vivax*
### Participants

- **Sample size:** 291
- **Age:** All age groups eligible. Actual age range of participants 1 to 60 years
- **Sex:** Both males and females eligible. Male: female ratio 1:1.15
- **Co-morbidities and pregnancy:** No criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population presented
- **Parasite density of microscopy positive cases:** Range 80 to 111,920 parasites per µL, mean 8011, standard deviation 21,595

### Study design

- Enrolment was consecutive and prospective. 1 RDT was evaluated

### Target condition and reference standard(s)

- **Target condition:** Malaria parasitaemia
- **Reference standard:** Microscopy thick blood films
- **Who performed the reference standard tests, and where?** Experienced microscopist in the laboratory of NIMR
- **If microscopy was used, how many high power fields were looked at?** 100
- **How many observers or repeats were used?** 1 for all samples, 2 independent readers for samples discordant between microscopy and RDT
- **How were discrepancies between observers resolved?** Where the second reading gave a different result from the first, the results of the second reading were confirmed by a third examination by another technician

### Index and comparator tests

- **Commercial name of RDT:** First Response Combo Malaria Ag card test (Premier Medical Corporation Ltd, Mumbai, India)
- **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only
- **Designated type:** Type 3
- **Batch numbers:** 61F0107
- **Transport and storage conditions:** RDTs were stored properly, at temperature of 4°C to 30°C, and used within their shelf life
- **Person(s) performing RDT:** Field laboratory assistants. Independent staff re-read the saved tests after 2 months and matched them with the originally recorded results
- **RDT setting:** Field laboratory

### Follow-up

- Not applicable

### Notes

- **Source of funding:** Indian Council of Medical Research, Delhi. Test kits provided by Premier Medical Corporation Ltd

### Table of Methodological Quality

| Item                        | Authors' judgement | Description                                                                                                                                 |
|-----------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?    | Yes                | Participants were a consecutive sample of people attending mobile field clinics with fever or history of fever, and suspicion of malaria |
| All tests                   |                    |                                                                                                                                            |
### Bharti 2008 (Continued)

| Acceptable reference standard? | Yes | An experienced microscopist viewed at least 100 high power fields before declaring a slide negative, and results discordant with RDT were independently re-examined by a second microscopist, and a third if necessary. |
|-------------------------------|-----|---|
| Partial verification avoided? | Yes | All participants who received the index test also received the reference test. |
| Differential verification avoided? | Yes | The same reference test was used regardless of the index test results. |
| Incorporation avoided? | Yes | The index test does not form part of the reference standard. |
| Reference standard results blinded? | Yes | Microscopy was undertaken “without reference to the RDT”. |
| Index test results blinded? | Yes | RDTs were undertaken on site, and the results recorded before the microscopy results became available. |
| Uninterpretable results reported? | Yes | The paper reported that there were no invalid results. |
| Withdrawals explained? | Yes | The number of participants enrolled in the study was clearly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals. |

### Chanie 2011

#### Clinical features and settings

- **Presenting signs and symptoms:** Suspected malaria: clinical symptoms of malaria, fever
- **Previous treatments for malaria:** 12.5% of the subjects had anti-malaria treatment in the preceding month
- **Clinical setting:** Outpatient departments of 3 health facilities
- **Country:** Ethiopia
- **Malaria endemicity:** High endemicity
- **Malaria endemic species:** *P. falciparum* and *P. vivax*

#### Participants

- **Sample size:** 1092
- **Age:** Mean 22.3 (SD 12.8); range 3 months to 78 years of age
- **Sex:** 48.57% female, 51.43% male
- **Co-morbidities or pregnancy:** Co-morbidities and pregnancy not stated

#### Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT.
### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*

**Reference standard test(s) used:** Microscopy thick and thin smears

**Who performed the reference standard tests, and where?** Experienced malaria technicians performed the microscopic test. Location not reported (presumably at each of the participating health centres)

**If microscopy was used, how many high power fields were looked at?** A minimum of 100 high power fields examined on a thick smear

**How many observers or repeats were used?** Not stated

**How were discrepancies between observers resolved?** 20% of the positive and 10% of the negative slides and discordant results between RDT and microscopic tests were examined by another well experienced technician

### Index and comparator tests

**Commercial name of the test:** CareStart Malaria Pf/Pv Combo (Access Bio Inc, New Jersey, USA)

**Parasite species the test is designed to detect:** *P. falciparum* and *P. vivax*

**Designated type:** Type Other (HRP-2 antigen for *P. falciparum* and pLDH antigen for *P. vivax*)

**Batch numbers:** Lot No H38 IV and Lot No H28 IV

**Transport and storage conditions:** Lot No H38 IV and Lot No H28 IV

**Who performed the index test, and where?** Experienced malaria technicians performed the index test

### Follow-up

**Not applicable**

### Notes

**Source of funding:** Addis Ababa University, The Federal Ministry of Health of Ethiopia. RDT kits were donated by Acces Bio Inc

### Table of Methodological Quality

| Item                                      | Authors' judgement | Description                                                                 |
|-------------------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum? All tests        | Yes                | All participants were attending primary health centres with fever and symptoms of malaria, sampling was consecutive |
| Acceptable reference standard? All tests  | Yes                | “...discordant results between RDT and microscopic tests were examined by another well experienced technician”. Experienced malaria technicians viewed 200 white blood cells or 100 fields |
| Partial verification avoided? All tests   | Yes                | Characteristics of participants are well described and the only exclusion criterion was refusal to participate in the study |
| Differential verification avoided? All tests | Yes             | The same reference standard was used.                                      |
### Chanie 2011 (Continued)

| Question                                      | All tests | Note                                                                                                                                 |
|-----------------------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------|
| Incorporation avoided?                        | Yes       | The reference standard was microscopy.                                                                                             |
| Reference standard results blinded?           | Unclear   | Blinding procedures not stated. However, microscopic evaluation and RDT were performed independently. Results were recorded in separate sheets |
| Index test results blinded?                   | Unclear   | Blinding procedures not stated. However, microscopic evaluation and RDT were performed independently. Results were recorded in separate sheets |
| Uninterpretable results reported?             | Unclear   | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained?                        | Yes       | The number recruited into the study was clearly stated, and corresponded with the number included in the analysis, therefore there were no withdrawals |

### Chayani 2004

**Clinical features and settings**

- **Presenting signs and symptoms:** Specific symptoms: rigor, chills, rise of high temperature and profuse sweating; or irregular fever, joint pain and jaundice
- **Previous treatment for malaria:** No explicit exclusions based on previous treatment and no information presented on previous treatment
- **Clinical setting:** Diagnostic and research centre (takes referrals from physicians for the diagnosis of malaria)
- **Country:** Orissa, India
- **Malaria endemicity:** Not stated
- **Malaria endemic species:** In sample, 78.6% *P. falciparum*, 21.4% *P. vivax*

**Participants**

- **Sample size:** 232
- **Age:** Not mentioned, either as inclusion criteria or characteristic of participants
- **Sex:** Not mentioned, either as inclusion criteria or characteristic of participants
- **Co-morbidities and pregnancy:** Not mentioned, either as inclusion criteria or characteristic of participants
- **Parasite density of microscopy positive cases:** Not presented

**Study design**

- Enrolment was prospective. The sampling method was unclear. 1 RDT was evaluated

**Target condition and reference standard(s)**

- **Target condition:** Malaria parasitaemia
- **Reference standard:** Microscopy thick and think blood smear
- **Who performed the reference standard tests, and where?** Microscopists in a diagnostic and research centre
If microscopy was used, how many high power fields were looked at? 200
How many observers or repeats were used? 2 independent observers
How were discrepancies between observers resolved? A third microscopist’s opinion was taken into account

| Index and comparator tests                  | Commerical name of RDT: OptiMAL (DiaMed, AG, Cressier, Switzerland) |
|                                           | Parasite(s) designed to detect: *P. falciparum* or mixed infection, non-falciparum malaria species only |
|                                           | Designated type: Type 4 |
|                                           | Batch numbers: Not stated |
|                                           | Transport and storage conditions: Not described |
|                                           | Person(s) performing RDT: Not stated |
|                                           | RDT setting: Not stated |

Follow-up

Not applicable

Notes

Source of funding: Not stated

### Table of Methodological Quality

| Item                           | Authors’ judgement | Description                                                                 |
|-------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum? All tests | Unclear            | All participants were attending an ambulatory clinic with rigor, chills, rise of high temperature and profuse sweating; or irregular fever, joint pain and jaundice. However the sampling method was not described |
| Acceptable reference standard? All tests | Yes                | 2 independent microscopists viewed 200 high powered fields before declaring a slide negative |
| Partial verification avoided? All tests | Yes                | All participants who received the index test also received the reference test |
| Differential verification avoided? All tests | Yes                | The same reference test was used regardless of the index test results |
| Incorporation avoided? All tests | Yes                | The index test does not form part of the reference standard. |
| Reference standard results blinded? All tests | Unclear            | Blinding not described. |
| Index test results blinded? All tests | Unclear            | Blinding not described. |
| Uninterpretable results reported? All tests | No                 | The number of participants originally enrolled in the study was not explicitly stated; |
Chayani 2004  *(Continued)*

| Withdrawals explained? All tests | Unclear | The number of participants originally enrolled in the study was not explicitly stated; therefore it is not possible to judge whether there were any withdrawals |

Dev 2004

| Clinical features and settings | Presenting signs and symptoms: Fever Previous treatment for malaria: No information presented on previous treatment; no suggestion of any exclusions based on previous treatment Clinical setting: Malaria clinics Country: India (Assam) Malaria endemicity: Mesoendemic Malaria endemic species: *P. falciparum* and *P. vivax* |
| Participants | Sample size: 336; but varied by RDT evaluated (10 to 139) Age: Infants under 12 months excluded; actual age range 1 to 60 years Sex: Both males and females eligible. Actual proportions of males and females in the participant population not stated Co-morbidities and pregnancy: No exclusions criteria based on co-morbidities or pregnancy were stated, and no details of the frequency of these conditions in the participant population is presented Parasite density of microscopy positive cases: Range 300 to 350,000 parasites per µL, mean 59,842, standard deviation (SD) 78,780 |
| Study design | Enrolment was prospective. The sampling method was not described. 7 RDTs were evaluated; it is unclear how each RDT was allocated, as no participant received all the tests |
| Target condition and reference standard(s) | Target condition: Malaria parasitaemia Reference standard: Microscopy thick and thin blood smears Who performed the reference standard tests, and where? Technician; all positive slides and 20% of negative slides were also examined by the senior technician for confirmation of result. Setting was the laboratory at the malaria clinics If microscopy was used, how many high power fields were looked at? 100 How many observers or repeats were used? 1 in the case of most smears judged negative by the technician. 2 in the case of 20% of those initially judged negative, and all those judged positive How were discrepancies between observers resolved? The judgement of the senior technician was used |
| Index and comparator tests | Commerical name of RDT: Paracheck Pf (Orchid Biomedical Systems, Goa, India) ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ) ParaHIT-F (Span diagnostics Ltd, Surat, India) |

*Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)*

Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
Parasite(s) designed to detect:
- Paracheck Pf - *P. falciparum*
- ParaSight-F - *P. falciparum*
- ParaHIT-F - *P. falciparum*
- ICT Malaria Pf - *P. falciparum*
- New Pf-1 mini - *P. falciparum*
- SD Malaria Pf/Pv - *P. falciparum* or mixed infection, non-falciparum malaria species only
- Diamed OptiMAL - *P. falciparum* or mixed infection, non-falciparum malaria species only

Designated type:
- Paracheck Pf - Type I
- ParaSight-F - Type I
- ParaHIT-F - Type I
- ICT Malaria Pf - Type I
- New Pf-1 mini - Type I
- SD Malaria Pf/Pv - Type 3
- Diamed OptiMAL - Type 4

Batch numbers: Not stated

Transport and storage conditions: Not described

Person(s) performing RDT: The laboratory attendant performed the test and recorded his or her interpretation. The test kit result was then re-read for verification by the senior technician

RDT setting: Malaria clinic laboratory

Follow-up
Not applicable

Notes
Source of funding: Mian source of funding not stated. Test kits supplied by the Government of Assam

Table of Methodological Quality

| Item                          | Authors’ judgement | Description |
|-------------------------------|--------------------|-------------|
| Representative spectrum?      | Unclear            | All participants were attending malaria clinics with fever; however, during the study period, 6663 blood smears were examined but only 336 were evaluated with RDT kits, and the sampling method for RDT evaluation was unclear |
| Acceptable reference standard?| Unclear            | 2 observers were used in the vast majority of cases; however, it is unclear whether the observers worked independently |
Partial verification avoided?  
All tests  | Yes  | All participants who received the index test also received the reference test.

Differential verification avoided?  
All tests  | Yes  | The same reference test was used regardless of the index test results.

Incorporation avoided?  
All tests  | Yes  | The index test does not form part of the reference standard.

Reference standard results blinded?  
All tests  | Yes  | Microscopy and RDT results were compared by an independent observer.

Index test results blinded?  
All tests  | Yes  | Microscopy and RDT results were compared by an independent observer.

Uninterpretable results reported?  
All tests  | No  | No information presented on numbers initially allocated each RDT, so not possible to judge this.

Withdrawals explained?  
All tests  | Unclear  | No information presented on numbers initially allocated each RDT, so not possible to judge this.

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Eibach 2013

**Clinical features and settings**

*Presenting signs and symptoms:* Suspected malaria with a temperature > 37.5°C  
*Previous treatments for malaria:* More than 90% of the patients reported receiving traditional or registered drugs, including antipyretics, antimalarials and antibiotics previously. However, the quality of drugs, the dosage and the duration of treatment remained unknown  
*Clinical setting:* General health centre  
*Country:* Mali  
*Malaria endemicity:* Hyperendemic in the peripheral villages, mesoendemic in the periurban area and hypoendemic in the city  
*Malaria endemic species:* 95% *P. falciparum*

**Participants**

*Sample size:* 727  
*Age:* Mean 23.5 (SD 14.9) median = 21, range 1 to 60  
*Sex:* Not reported  
*Co-morbidities or pregnancy:* Not reported

**Study design**

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 2 RDTs

**Target condition and reference standard(s)**

*Type(s) of malaria parasite tested for:* *P. falciparum*, PAN malaria  
*Reference standard test(s) used:* Microscopy thick and thin smears  
*Who performed the reference standard tests, and where:* Local investigators  
*If microscopy was used, how many high power fields were looked at:* 100
How many observers or repeats were used? Thick and thin smears were assessed by 2 local investigators, and by an expert at the Parasitology Department of the Lyon University Hospital, as a quality control.

How were discrepancies between observers resolved? Local investigators resolved all discrepancies between themselves by consensus. All discordant results between microscopy and the 2 RDTs were resolved by PCR and test characteristics were recalculated according to the PCR-corrected results.

Index and comparator tests

Commercial name of the test: VIKIA Malaria Ag Pf/Pan (IMAccess, Lyon, France), CareStart Malaria (AccessBio, USA)

Parasite species the test is designed to detect: VIKIA Malaria Ag Pf/Pan: *P. falciparum* or mixed infection, non-falciparum malaria species only
CareStart Malaria: *P. falciparum* or mixed infection, non-falciparum malaria species only

Designated type: VIKIA Malaria Ag Pf/Pan: Type 2
CareStart Malaria: Type 3

Batch numbers: VIKIA Malaria Ag Pf/Pan: RD_MA2_110527
CareStart Malaria: G21MR

Transport and storage conditions: Not reported

Who performed the index test, and where? Local community health workers trained to use both tests.

Follow-up

Not applicable

Notes

Source of funding: The study was supported by IMACCESS.

Data from the Lyon part of the study was not included as it did not match inclusion criteria.

The VIKIA Malaria Ag Pf/Pan™ test was read at different time points (15, 20, 30, 60 minutes), while the CareStart Malaria™ test was read after 20 minutes as recommended.

2 drops of blood were spotted onto filter paper, individually stored in a plastic bag and sent to the Parasitology Department of the Lyon University Hospital for PCR correction.

| Table of Methodological Quality |
|--------------------------------|
| **Item**                        | **Authors’ judgement** | **Description**                                    |
|---------------------------------|------------------------|----------------------------------------------------|
| Representative spectrum?        | Yes                    | Consecutive sample of people attending a clinic with symptoms of malaria |
| All tests                        |                        |                                                    |
| Acceptable reference standard?  | Yes                    | Microscopy was undertaken by 2 trained local health workers and corrected by PCR at the Parasitology Department of the Lyon University Hospital |
| All tests                        |                        |                                                    |
| Partial verification avoided?   | Yes                    | All participants who received the index test also received the reference tests |
| All tests                        |                        |                                                    |
| Differential verification avoided? | Yes              | The same reference test was used.                 |
| All tests                        |                        |                                                    |
### Incorporation avoided?

All tests | Yes | Standard microscopy and PCR.

### Reference standard results blinded?

All tests | Yes | All microscopists were blinded to the results of the RDTs.

### Index test results blinded?

All tests | Yes | RDTs were performed immediately after sampling.

### Uninterpretable results reported?

All tests | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results.

### Withdrawals explained?

All tests | Yes | The number of participants enrolled was clearly stated, and the number included in the analysis corresponds to this number, indicating no withdrawals.

### Elahi 2013

#### Clinical features and settings

- **Presenting signs and symptoms:** Febrile patients with clinical symptoms
- **Previous treatments for malaria:** Not described
- **Clinical setting:** Health posts in remote border areas
- **Country:** Bangladesh
- **Malaria endemicity:** Endemic
- **Malaria endemic species:** 74% *P. falciparum*, 26% *P. vivax*, *P. malariae* and *P. ovale* were also present in the area, but were not found within the study sample

#### Participants

- **Sample size:** 327
- **Age:** Not reported
- **Sex:** Not reported
- **Co-morbidities or pregnancy:** Not reported

#### Study design

- Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

#### Target condition and reference standard(s)

- **Type(s) of malaria parasite tested for:** *P. falciparum*, PAN malaria
- **Reference standard test(s) used:** Microscopy thick and thin smears; quantitative PCR
- **Who performed the reference standard tests, and where?** Experienced microscopists at the field sites
- **If microscopy was used, how many high power fields were looked at?** 100
- **How many observers or repeats were used?** 2 independent microscopists, blinded to the findings of the other
- **How were discrepancies between observers resolved?** Where there was a discrepancy between the 2 microscopists, the sample was excluded from the study. The number excluded for this reason was not stated
Index and comparator tests

Commercial name of the test: Parascreen (Zephyr Biomedical Systems, India)
Parasite species the test is designed to detect: *P. falciparum* or mixed infection, non-*falciparum* malaria species only
Designated type: Type 3
Batch numbers: 101159
Transport and storage conditions: Not described
Who performed the index test, and where? Laboratory personnel at the Parisitology Laboratory, icddr,b

Follow-up
Not applicable

Notes
Source of funding: icddr,b and its donors, which provide unrestricted support to icddr,b for its operations and support. Parascreen was donated by the manufacturer

Table of Methodological Quality

| Item                                | Authors' judgement | Description |
|-------------------------------------|--------------------|-------------|
| Representative spectrum?            | Unclear            | Recruitment was prospective, but the sampling procedure was not stated. Samples with mixed infections or where the 2 microscopists’ findings did not agree were excluded, and the number excluded was not stated |
| Acceptable reference standard?      | Unclear            | Microscopy was undertaken by 2 experienced microscopists, but the number of fields viewed before declaring a slide negative was not stated |
| Partial verification avoided?       | Yes                | All participants received both the reference test and the index test |
| Differential verification avoided?   | Yes                | The same reference test was used regardless of the index test results |
| Incorporation avoided?              | Yes                | Microscopy was used as the reference standard. |
| Reference standard results blinded? | Yes                | Microscopists were blinded to prior results. |
| Index test results blinded?         | Unclear            | Blinding not described, however, index and reference tests were undertaken at different locations |
### Elahi 2013  (Continued)

| Uninterpretable results reported? | No | Uninterpretable results were not reported on. |
|-----------------------------------|----|-------------------------------------------|
| All tests                         |    |                                           |
| Withdrawals explained?            | No | It was stated that samples with mixed infection or where microscopists disagreed were excluded; however, the number of samples excluded and the original number of participants enrolled was not presented |
| All tests                         |    |                                           |

### Endeshaw 2012a

**Clinical features and settings**

**Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours  
**Previous treatments for malaria:** Not stated  
**Clinical setting:** Ten health centres  
**Country:** Ethiopia  
**Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection  
**Malaria endemic species:** Not stated

**Participants**

**Sample size:** 1997. 4 RDTs were not done (reason not reported)  
**Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)  
**Sex:** 56.2 male, 43.8 female  
**Co-morbidities or pregnancy:** Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

**Study design**

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

**Target condition and reference standard(s)**

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*  
**Reference standard test(s) used:** Microscopy, thick and thin smears  
**Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians  
**If microscopy was used, how many high power fields were looked at?** Not stated  
**How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa  
**How were discrepancies between observers resolved?** Not stated

**Index and comparator tests**

**Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)  
**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only  
**Designated type:** Type 3  
**Batch numbers:** Not stated  
**Transport and storage conditions:** Not stated  
**Who performed the index test, and where?** The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures
Endeshaw 2012a  (Continued)

| Item                              | Authors’ judgement | Description                                                                 |
|-----------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum?          | Yes                | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
| Acceptable reference standard?    | Unclear            | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field was not stated |
| Partial verification avoided?     | Yes                | All participants who received the index test also received the reference test |
| Differential verification avoided? | Yes                | The same reference test was used regardless of the index test results       |
| Incorporation avoided?            | Yes                | Microscopy was used as reference standard.                                  |
| Reference standard results blinded?| Yes                | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| Index test results blinded?       | Yes                | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians |
| Uninterpretable results reported? | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained?            | Yes                | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who de- |
| Endeshaw 2012a |  |
|----------------|----------------|
| **Continued** | **clinied to participate and 4 who did not have RDT because the technicians had too much work** |

| Endeshaw 2012b |  |
|----------------|----------------|
| **Clinical features and settings** | **Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours  
**Previous treatments for malaria:** Not stated  
**Clinical setting:** Ten health centres  
**Country:** Ethiopia  
**Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection  
**Malaria endemic species:** Not stated |
| **Participants** | **Sample size:** 1997. 4 RDTs were not done (reason not reported)  
**Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)  
**Sex:** 56.2 male, 43.8 female  
**Co-morbidities or pregnancy:** Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated |
| **Study design** | Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT |
| **Target condition and reference standard(s)** | **Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*  
**Reference standard test(s) used:** Microscopy, thick and thin smears  
**Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians  
**If microscopy was used, how many high power fields were looked at?** Not stated  
**How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa  
**How were discrepancies between observers resolved?** Not stated |
| **Index and comparator tests** | **Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)  
**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only  
**Designated type:** Type 3  
**Batch numbers:** Not stated  
**Transport and storage conditions:** Not stated  
**Who performed the index test, and where?** The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures |
| **Follow-up** | Not applicable |
| **Notes** | **Source of funding:** Not stated. “Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy.” |
"Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers."

### Table of Methodological Quality

| Item                                      | Authors’ judgement | Description                                                                                                                                 |
|-------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum? All tests        | Yes                | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
| Acceptable reference standard? All tests  | Unclear            | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic fields was not stated |
| Partial verification avoided? All tests   | Yes                | All participants who received the index test also received the reference test                                                                |
| Differential verification avoided? All tests | Yes                | The same reference test was used regardless of the index test results                                                                         |
| Incorporation avoided? All tests          | Yes                | Microscopy was used as a reference standard                                                                                                  |
| Reference standard results blinded? All tests | Yes                | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| Index test results blinded? All tests     | Yes                | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians                                                      |
| Uninterpretable results reported? All tests | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained? All tests          | Yes                | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
Presenting signs and symptoms: Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours.

Previous treatments for malaria: Not stated.

Clinical setting: Ten health centres.

Country: Ethiopia.

Malaria endemicity: The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection.

Malaria endemic species: Not stated.

Sample size: 1997. 4 RDTs were not done (reason not reported).

Age: Range: 8 months to 85 years. Mean 20.7 (SD not stated).

Sex: 56.2 male, 43.8 female.

Co-morbidities or pregnancy: Patients with other known causes of non-malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated.

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT.

Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*.

Reference standard test(s) used: Microscopy, thick and thin smears.

Who performed the reference standard tests, and where? Microscopy assessment was performed by experienced medical laboratory technicians.

If microscopy was used, how many high power fields were looked at? Not stated.

How many observers or repeats were used? Slides were also sent for expert microscopy at The Carter Center in Addis Ababa.

How were discrepancies between observers resolved? Not stated.

Commercial name of the test: ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India).

Parasite species the test is designed to detect: *P. falciparum* or mixed infection, non-*falciparum* malaria species only.

Designated type: Type 3.

Batch numbers: Not stated.

Transport and storage conditions: Not stated.

Who performed the index test, and where? The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures.

Source of funding: Not stated.

"Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy."

"Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers."
| Feature                                      | All tests | Notes                                                                                                                                 |
|----------------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                     | Yes       | In each health centre, the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
| Acceptable reference standard?               | Unclear   | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated |
| Partial verification avoided?                | Yes       | All participants who received the index test also received the reference test                                                                 |
| Differential verification avoided?           | Yes       | The same reference test was used regardless of the index test results                                                                 |
| Incorporation avoided?                       | Yes       | Microscopy was used as reference standard.                                                                                                                                                     |
| Reference standard results blinded?          | Yes       | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| Index test results blinded?                  | Yes       | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians                                                                                                        |
| Uninterpretable results reported?            | Unclear   | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained?                       | Yes       | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
Presenting signs and symptoms: Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours

Previous treatments for malaria: Not stated
Clinical setting: Ten health centres
Country: Ethiopia
Malaria endemicity: The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection
Malaria endemic species: Not stated

Sample size: 1997. 4 RDTs were not done (reason not reported)
Age: Range: 8 months to 85 years. Mean 20.7 (SD not stated)
Sex: 56.2 male, 43.8 female
Co-morbidities or pregnancy: Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*
Reference standard test(s) used: Microscopy, thick and thin smears
Who performed the reference standard tests, and where? Microscopy assessment was performed by experienced medical laboratory technicians
If microscopy was used, how many high power fields were looked at? Not stated
How many observers or repeats were used? Slides were also sent for expert microscopy at The Carter Center in Addis Ababa
How were discrepancies between observers resolved? Not stated

Commercial name of the test: ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)
Parasite species the test is designed to detect: *P. falciparum* or mixed infection, non-falciparum malaria species only
Designated type: Type 3
Batch numbers: Not stated
Transport and storage conditions: Not stated
Who performed the index test, and where? The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

Source of funding: Not stated.
"Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy."
"Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers."

| Item | Authors’ judgement | Description |
|------|--------------------|-------------|
| Item | Authors’ judgement | Description |

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)
| Test | Representative spectrum? | Yes | In each health centre, the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
|------|--------------------------|-----|------------------------------------------------------------------------------------------------------------------|
|      | Acceptable reference standard? | Unclear | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, the number of microscopic fields was not stated |
|      | Partial verification avoided? | Yes | All participants who received the index test also received the reference test |
|      | Differential verification avoided? | Yes | The same reference test was used regardless of the index test results |
|      | Incorporation avoided? | Yes | Microscopy was used as reference standard. |
|      | Reference standard results blinded? | Yes | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
|      | Index test results blinded? | Yes | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians |
|      | Uninterpretable results reported? | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
|      | Withdrawals explained? | Yes | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
**Endeshaw 2012e**

**Clinical features and settings**
- **Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours
  - **Previous treatments for malaria:** Not stated
  - **Clinical setting:** Ten health centres
  - **Country:** Ethiopia
  - **Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection
  - **Malaria endemic species:** Not stated

**Participants**
- **Sample size:** 1997. 4 RDTs were not done (reason not reported)
- **Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)
- **Sex:** 56.2 male, 43.8 female
- **Co-morbidities or pregnancy:** Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

**Study design**
- Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

**Target condition and reference standard(s)**
- **Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*
- **Reference standard test(s) used:** Microscopy, thick and thin smears
- **Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians
- **If microscopy was used, how many high power fields were looked at?** Not stated
- **How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa
- **How were discrepancies between observers resolved?** Not stated

**Index and comparator tests**
- **Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)
- **Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only
- **Designated type:** Type 3
- **Batch numbers:** Not stated
- **Transport and storage conditions:** Not stated
- **Who performed the index test, and where?** The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

**Follow-up**
- **Not applicable**

**Notes**
- **Source of funding:** Not stated.
  - “Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy.”
  - “Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers.”

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**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
|------|---------------------|-------------|

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Rapid diagnostic tests for diagnosing uncomplicated non-*falciparum* or *Plasmodium vivax* malaria in endemic countries (Review) 87
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
### Representative spectrum?
**All tests**
**Yes**
In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited.

### Acceptable reference standard?
**All tests**
**Unclear**
Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated.

### Partial verification avoided?
**All tests**
**Yes**
All participants who received the index test also received the reference test.

### Differential verification avoided?
**All tests**
**Yes**
The same reference test was used regardless of the index test results.

### Incorporation avoided?
**All tests**
**Yes**
Microscopy was used as reference standard.

### Reference standard results blinded?
**All tests**
**Yes**
Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion.

### Index test results blinded?
**All tests**
**Yes**
Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians.

### Uninterpretable results reported?
**All tests**
**Unclear**
Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results.

### Withdrawals explained?
**All tests**
**Yes**
Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work.
Endeshaw 2012f

### Clinical features and settings

**Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours

**Previous treatments for malaria:** Not stated

**Clinical setting:** Ten health centres

**Country:** Ethiopia

**Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection

**Malaria endemic species:** Not stated

### Participants

**Sample size:** 1997. 4 RDTs were not done (reason not reported)

**Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)

**Sex:** 56.2 male, 43.8 female

**Co-morbidities or pregnancy:** Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

### Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*

**Reference standard test(s) used:** Microscopy, thick and thin smears

**Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians

**If microscopy was used, how many high power fields were looked at?** Not stated

**How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa

**How were discrepancies between observers resolved?** Not stated

### Index and comparator tests

**Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)

**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only

**Designated type:** Type 3

**Batch numbers:** Not stated

**Transport and storage conditions:** Not stated

**Who performed the index test, and where?** The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

### Follow-up

Not applicable

### Notes

**Source of funding:** Not stated.

“Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy.”

“Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers.”

### Table of Methodological Quality

| Item | Authors’ judgement | Description |
|------|--------------------|-------------|

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**Rapid diagnostic tests for diagnosing uncomplicated non-*falciparum* or *Plasmodium vivax* malaria in endemic countries (Review)**

Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
| Quality Assessment Item                                                                 | Yes/No | Description                                                                                                                                                 |
|----------------------------------------------------------------------------------------|--------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                                                               | Yes    | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited.         |
| Acceptable reference standard?                                                          | Unclear| Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated. |
| Partial verification avoided?                                                           | Yes    | All participants who received the index test also received the reference test.                                                                              |
| Differential verification avoided?                                                       | Yes    | The same reference test was used regardless of the index test results.                                                                                     |
| Incorporation avoided?                                                                  | Yes    | Microscopy was used as reference standard.                                                                                                                  |
| Reference standard results blinded?                                                     | Yes    | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion. |
| Index test results blinded?                                                             | Yes    | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians.                                                                   |
| Uninterpretable results reported?                                                       | Unclear| Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results. |
| Withdrawals explained?                                                                 | Yes    | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work. |
**Endeshaw 2012g**

**Clinical features and settings**

- **Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours
- **Previous treatments for malaria:** Not stated
- **Clinical setting:** Ten health centres
- **Country:** Ethiopia
- **Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection
- **Malaria endemic species:** Not stated

**Participants**

- **Sample size:** 1997. 4 RDTs were not done (reason not reported)
- **Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)
- **Sex:** 56.2 male, 43.8 female
- **Co-morbidities or pregnancy:** patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

**Study design**

- Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

**Target condition and reference standard(s)**

- **Type(s) of malaria parasite tested for:** P. falciparum and P. vivax
- **Reference standard test(s) used:** Microscopy, thick and thin smears
- **Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians
- **If microscopy was used, how many high power fields were looked at?** Not stated
- **How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa
- **How were discrepancies between observers resolved?** Not stated

**Index and comparator tests**

- **Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)
- **Parasite species the test is designed to detect:** P. falciparum or mixed infection, non-falciparum malaria species only
- **Designated type:** Type 3
- **Batch numbers:** Not stated
- **Transport and storage conditions:** Not stated
- **Who performed the index test, and where?** The 10 experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

**Follow-up**

- Not applicable

**Notes**

- **Source of funding:** Not stated.
  - “Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy”
  - “Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers.”

**Table of Methodological Quality**

| Item | Authors' judgement | Description |
|------|--------------------|-------------|

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)  
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
Endeshaw 2012g  (Continued)

|                                  | Yes | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
|----------------------------------|-----|-------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?         | Yes | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated |
| Acceptable reference standard?   | Unclear | All participants who received the index test also received the reference test |
| Partial verification avoided?    | Yes | The same reference test was used regardless of the index test results |
| Differential verification avoided?| Yes | Microscopy was used as reference standard. |
| Incorporation avoided?           | Yes | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| Reference standard results blinded? | Yes | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians |
| Index test results blinded?      | Yes | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Uninterpretable results reported?| Unclear | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
| Withdrawals explained?           | Yes | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
Endeshaw 2012h

Clinical features and settings

Presenting signs and symptoms: Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours
Previous treatments for malaria: Not stated
Clinical setting: Ten health centres
Country: Ethiopia
Malaria endemicity: The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection
Malaria endemic species: Not stated

Participants

Sample size: 1997. 4 RDTs were not done (reason not reported)
Age: Range: 8 months to 85 years. Mean 20.7 (SD not stated)
Sex: 56.2 male, 43.8 female
Co-morbidities or pregnancy: patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

Target condition and reference standard(s)

Type(s) of malaria parasite tested for: P. falciparum and P. vivax
Reference standard test(s) used: Microscopy, thick and thin smears
Who performed the reference standard tests, and where? Microscopy assessment was performed by experienced medical laboratory technicians
If microscopy was used, how many high power fields were looked at? Not stated
How many observers or repeats were used? Slides were also sent for expert microscopy at The Carter Center in Addis Ababa
How were discrepancies between observers resolved? Not stated

Index and comparator tests

Commercial name of the test: ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa,India)
Parasite species the test is designed to detect: P. falciparum or mixed infection, non-falciparum malaria species only
Designated type: Type 3
Batch numbers: Not stated
Transport and storage conditions: Not stated
Who performed the index test, and where? The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

Follow-up

Not applicable

Notes

Source of funding: Not stated.
“Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy.”
“Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers.”

Table of Methodological Quality

| Item | Authors’ judgement |
|------|-------------------|

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or Plasmodium vivax malaria in endemic countries (Review)
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
| Study | Question | Outcome | Description |
|-------|----------|---------|-------------|
| Endeshaw 2012h | Representative spectrum? <br> All tests | Yes | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
| | Acceptable reference standard? <br> All tests | Unclear | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated |
| | Partial verification avoided? <br> All tests | Yes | All participants who received the index test also received the reference test |
| | Differential verification avoided? <br> All tests | Yes | The same reference test was used regardless of the index test results |
| | Incorporation avoided? <br> All tests | Yes | Microscopy was used as reference standard. |
| | Reference standard results blinded? <br> All tests | Yes | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| | Index test results blinded? <br> All tests | Yes | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians |
| | Uninterpretable results reported? <br> All tests | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| | Withdrawals explained? <br> All tests | Yes | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
### Clinical features and settings

**Presenting signs and symptoms:** Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours

**Previous treatments for malaria:** Not stated

**Clinical setting:** Ten health centres

**Country:** Ethiopia

**Malaria endemicity:** The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection

**Malaria endemic species:** Not stated

### Participants

**Sample size:** 1997. 4 RDTs were not done (reason not reported)

**Age:** Range: 8 months to 85 years. Mean 20.7 (SD not stated)

**Sex:** 56.2 male, 43.8 female

**Co-morbidities or pregnancy:** Patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

### Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*

**Reference standard test(s) used:** Microscopy, thick and thin smears

**Who performed the reference standard tests, and where?** Microscopy assessment was performed by experienced medical laboratory technicians

**If microscopy was used, how many high power fields were looked at?** Not stated

**How many observers or repeats were used?** Slides were also sent for expert microscopy at The Carter Center in Addis Ababa

**How were discrepancies between observers resolved?** Not stated

### Index and comparator tests

**Commercial name of the test:** ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)

**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-*falciparum* malaria species only

**Designated type:** Type 3

**Batch numbers:** Not stated

**Transport and storage conditions:** Not stated

**Who performed the index test, and where?** The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

### Follow-up

Not applicable

### Notes

**Source of funding:** Not stated.

“Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy.”

“Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers.”

### Table of Methodological Quality

| Item | Authors' judgement | Description |
|------|--------------------|-------------|
| Question                                                                 | All tests | Description                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------|-----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                                                | Yes       | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited                                                                                                                                                                                                                                                                                                                                       |
| Acceptable reference standard?                                          | Unclear   | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated                                                                                                                                                                                                                                                                                                           |
| Partial verification avoided?                                           | Yes       | All participants who received the index test also received the reference test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Differential verification avoided?                                      | Yes       | The same reference test was used regardless of the index test results                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Incorporation avoided?                                                 | Yes       | Microscopy was used as reference standard.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Reference standard results blinded?                                    | Yes       | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion                                                                                                                                                                                                                                                                                                                                                     |
| Index test results blinded?                                             | Yes       | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Uninterpretable results reported?                                      | Unclear   | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results                                                                                                                                                                                                                                                                                                                                  |
| Withdrawals explained?                                                 | Yes       | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work                                                                                                                                                                                                                      |
Presenting signs and symptoms: Clinically presumptive malaria: an axillary temperature greater than or equal to 37.5°C or history of fever in the previous 48 hours

Previous treatments for malaria: Not stated

Clinical setting: Ten health centres

Country: Ethiopia

Malaria endemicity: The study was conducted in an area with range of transmission intensities, during the peak transmission period of malaria infection

Malaria endemic species: Not stated

Sample size: 1997. 4 RDTs were not done (reason not reported)

Age: Range: 8 months to 85 years. Mean 20.7 (SD not stated)

Sex: 56.2 male, 43.8 female

Co-morbidities or pregnancy: patients with other known causes of non malarial febrile illnesses or serious illness were excluded. Pregnancy status not stated

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*

Reference standard test(s) used: Microscopy, thick and thin smears

Who performed the reference standard tests, and where? Microscopy assessment was performed by experienced medical laboratory technicians

If microscopy was used, how many high power fields were looked at? Not stated

How many observers or repeats were used? Slides were also sent for expert microscopy at The Carter Center in Addis Ababa

How were discrepancies between observers resolved? Not stated

Commercial name of the test: ParaScreen Pan/Pf (Zephyr Biomedical systems, Verna, Goa, India)

Parasite species the test is designed to detect: *P. falciparum* or mixed infection, non-falciparum malaria species only

Designated type: Type 3

Batch numbers: Not stated

Transport and storage conditions: Not stated

Who performed the index test, and where? The ten experienced laboratory technicians involved in this study were trained on the RDT sampling and evaluation procedures

Follow-up: Not applicable

Source of funding: Not stated.

"Out of 2000 recruited patients, 1997 febrile cases were examined for malaria parasites by blood slide microscopy."

"Of the 1997 persons tested by slide, 1993 samples were also examined by ParaScreen RDT at the health centers."

| Item | Authors' judgement | Description |
|------|--------------------|-------------|

Table of Methodological Quality
### Endeshaw 2012 (Continued)

| Feature                                      | All tests | Details                                                                                                                                 |
|----------------------------------------------|-----------|----------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                     | Yes       | In each health centre the first 200 self-presenting patients of any age and either sex who qualified as clinically presumptive malaria were recruited |
| Acceptable reference standard?               | Unclear   | Slides were evaluated by trained technicians at each site and were also sent to a central lab for expert microscopy. However, number of microscopic field have not been stated |
| Partial verification avoided?                | Yes       | All participants who received the index test also received the reference test                                                          |
| Differential verification avoided?           | Yes       | The same reference test was used regardless of the index test results                                                                     |
| Incorporation avoided?                       | Yes       | Microscopy was used as reference standard.                                                                                               |
| Reference standard results blinded?          | Yes       | Although blind procedures for local technicians are not reported, slides were also sent for expert microscopy at a central lab where they were examined in blinded fashion |
| Index test results blinded?                  | Yes       | Microscopy and ParaScreen Pan/PfH RDT were done immediately by health centre technicians                                                   |
| Uninterpretable results reported?            | Unclear   | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained?                       | Yes       | Number enrolled in the study was explicitly stated as 2000, 1993 were presented in the analysis; therefore there were 7 withdrawals. These were explained as 3 who declined to participate and 4 who did not have RDT because the technicians had too much work |
**Clinical features and settings**

**Presenting signs and symptoms:** Fever or history of fever  
**Previous treatment for malaria:** No exclusions because of prior antimalarial use, and no data presented on the frequency of recent antimalarial use in the participants  
**Clinical setting:** A malaria research station and a malaria clinic  
**Country:** Sri Lanka  
**Malaria endemicity:** Not stated  
**Malaria endemic species:** *P. vivax* (70%) and *P. falciparum*

**Participants**

**Sample size:** 328  
**Age:** All ages above 5 years eligible; mean age 28.3 years (range 5 to 72 years)  
**Sex:** Both males and females eligible; 64% of the participants were males  
**Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented  
**Parasite density of microscopy positive cases:** Not presented

**Study design**

Enrolment was consecutive and prospective. 1 RDT was evaluated

**Target condition and reference standard(s)**

**Target condition:** Malaria parasitaemia  
**Reference standard:** Microscopy thick and think blood films  
**Who performed the reference standard tests, and where?** Trained microscopists at the clinics and in a laboratory  
**If microscopy was used, how many high power fields were looked at?** 400  
**How many observers or repeats were used?** 2 independent readers; 1 at the clinics and another in a laboratory  
**How were discrepancies between observers resolved?** There were no discrepancies between the 2 microscopists

**Index and comparator tests**

**Commercial name of RDT:** ICT Malaria Pf/Pv (Amrad-ICT, Sydney, Australia)  
**Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only  
**Designated type:** Type 2  
**Batch numbers:** Not stated  
**Transport and storage conditions:** Stored and used at room temperature which often exceeds 30°C  
**Person(s) performing RDT:** The researchers  
**RDT setting:** At the clinics

**Follow-up**

Not applicable

**Notes**

**Source of funding:** National Science Foundation, Sri Lanka

**Table of Methodological Quality**

| Item                  | Authors’ judgement | Description                                                                 |
|-----------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum? All tests | Yes                | Participants were a consecutive sample of people attending clinics with fever or history of fever |
### Fernando 2004

| Acceptable reference standard? | Yes | All independent trained microscopists viewed 400 high power fields before declaring a slide negative |
|-------------------------------|-----|--------------------------------------------------------------------------------------------------|
| Partial verification avoided? | Yes | All participants who received the index test also received the reference test |
| Differential verification avoided? | Yes | The same reference test was used regardless of the index test results |
| Incorporation avoided? | Yes | The index test does not form part of the reference standard |
| Reference standard results blinded? | Unclear | Blinding not described |
| Index test results blinded? | Unclear | Blinding not described |
| Uninterpretable results reported? | Unclear | The number of participants enrolled was clearly stated, and the number included in the analysis corresponds to this number, indicating no withdrawals |
| Withdrawals explained? | Yes | The number of participants enrolled was clearly stated, and the number included in the analysis corresponds to this number, indicating no withdrawals |

### Harani 2006

**Clinical features and settings**
- **Presenting signs and symptoms:** Clinical symptoms of malaria and history of fever over 37.5°C. People with known causes of fever other than malaria were excluded.
- **Previous treatment for malaria:** Patients who had been treated for malaria in the previous 4 weeks were excluded from the study.
- **Clinical setting:** Outpatient department of a reference hospital.
- **Country:** Pakistan.
- **Malaria endemicity:** Not stated.
- **Malaria endemic species:** *P. falciparum* and *P. vivax*.

**Participants**
- **Sample size:** 560.
- **Age:** All age groups eligible; actual age range of included participants 2 to 73 years.
- **Sex:** Both males and females eligible. Participants included 339 males and 221 females.
- **Co-morbidities and pregnancy:** Not mentioned, either as an inclusion criteria or characteristic of included participants.
- **Parasite density of microscopy positive cases:** Not presented.

**Study design**
- Enrolment was prospective. The sampling method was not described. 1 RDT was tested.
Target condition and reference standard(s) | **Target condition:** Malaria parasitaemia  
**Reference standard:** Microscopy thick and thin blood films

Who performed the reference standard tests, and where? | Senior technologist and principle author in the Department of Pathology and Microbiology, Aga Khan University

If microscopy was used, how many high power fields were looked at? | 200

How many observers or repeats were used? | Unclear, 2 microscopists were used but how they divided the work between them was not described

How were discrepancies between observers resolved? | Not applicable

Index and comparator tests | **Commercial name of RDT:** ICT Malaria Pf/Pv (Binax Inc. Portland, Maine, USA)
**Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only
**Designated type:** Type 2
**Batch numbers:** Not stated
**Transport and storage conditions:** Not described
**Person(s) performing RDT:** The second author
**RDT setting:** Microbiology section of Aga Khan University

Follow-up | Not applicable

Notes | **Source of funding:** Not stated

### Table of Methodological Quality

| Item | Authors’ judgement | Description |
|------|--------------------|-------------|
| Representative spectrum? All tests | Unclear | All participants were presenting at an outpatients department with symptoms of malaria and history of fever, but the sampling method was not described |
| Acceptable reference standard? All tests | Unclear | 2 microscopists at a University laboratory viewed 200 high power fields before declaring a slide negative; however, it is unclear how the 2 microscopists worked together |
| Partial verification avoided? All tests | Yes | All participants who received the index test also received the reference test |
| Differential verification avoided? All tests | Yes | The same reference test was used regardless of the index test results |
| Incorporation avoided? All tests | Yes | The index test does not form part of the reference standard. |
| Reference standard results blinded? All tests | Yes | “The microscopists were unaware of the microscopy results”. |
### Harani 2006 (Continued)

| Index test results blinded? | Yes | “These results were read by the second author who was blind to the microscopy results” |
| Uninterpretable results reported? | Unclear | The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no exclusions due to invalid results |
| Withdrawals explained? | Yes | The number of participants originally enrolled in the study was clearly stated, and corresponds with the number presented in the analysis; therefore there were no withdrawals due to invalid results |

### Kolaczinski 2004

**Clinical features and settings**
- **Presenting signs and symptoms**: Suspected malaria or febrile illness
- **Previous treatment for malaria**: No exclusion criteria based on previous use of antimalarials, and no data on previous antimalarial use of the participants was presented
- **Clinical setting**: Basic health units within an Afghan refugee camp
- **Country**: Pakistan (North West Frontier Province)
- **Malaria endemicity**: Not stated
- **Malaria endemic species**: 80% *P. vivax*, 20% *P. falciparum*

**Participants**
- **Sample size**: 499
- **Age**: All age groups eligible for inclusion; actual age range of the participants not stated
- **Sex**: Both males and females eligible for inclusion; actual age range of the participants not stated
- **Co-morbidities and pregnancy**: No exclusions based on co morbidities or pregnancy, and no data presented on the frequency of these conditions in the study population
- **Parasite density of microscopy positive cases**: Not presented

**Study design**
- Enrolment was consecutive and prospective. 1 RDT was tested.

**Target condition and reference standard(s)**
- **Target condition**: Malaria parasitaemia
- **Reference standard**: Microscopy thick and think blood films
- **Who performed the reference standard tests, and where?**: Microscopists in the basic health units within an Afghan refugee camp and HNI’s reference laboratory in Peshawar
- **If microscopy was used, how many high power fields were looked at?**: 100
- **How many observers or repeats were used?**: 2, 1 at the BHU and 1 at the reference laboratory
- **How were discrepancies between observers resolved?**: Unclear “all of the smears checked by the microscopist at each BHU were cross checked at HNI’s reference laboratory at Pashawar”
Index and comparator tests

- **Commercial name of RDT:** OptiMAL (DiaMed, AG, Cressier, Switzerland)
- **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum malaria species only
- **Designated type:** Type 4
- **Batch numbers:** Not stated
- **Transport and storage conditions:** Not described
- **Person(s) performing RDT:** Microscopists
- **RDT setting:** Basic health units

Follow-up

- Not applicable

Notes

- **Source of funding:** Not stated

**Table of Methodological Quality**

| Item                          | Authors' judgement | Description                                                                 |
|-------------------------------|--------------------|------------------------------------------------------------------------------|
| Representative spectrum?      | Yes                | Participants were a consecutive series of patients attending a basic health units with suspected malaria |
| All tests                     |                    |                                                                              |
| Acceptable reference standard?| Yes                | 2 microscopists, 1 working in a central laboratory, viewed at least 100 high power fields before declaring a slide negative |
| All tests                     |                    |                                                                              |
| Partial verification avoided? | Yes                | All participants who received the index test also received the reference test |
| All tests                     |                    |                                                                              |
| Differential verification avoided? | Yes             | The same reference test was used regardless of the index test results |
| All tests                     |                    |                                                                              |
| Incorporation avoided?        | Yes                | The index test does not form part of the reference standard.                 |
| All tests                     |                    |                                                                              |
| Reference standard results blinded? | No            | The index test and reference test were undertaken by the same person |
| All tests                     |                    |                                                                              |
| Index test results blinded?   | No                 | The index test and reference test were undertaken by the same person         |
| All tests                     |                    |                                                                              |
| Uninterpretable results reported? | Unclear         | The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results |
| All tests                     |                    |                                                                              |
| Withdrawals explained?        | Yes                | The number of participants originally enrolled in the study was clearly stated, and |
corresponded to the number presented in the analysis: therefore there were no withdrawals

### Kosack 2013

#### Clinical features and settings

| Presenting signs and symptoms | Fever or a history of fever in the prior 24 hours |
|-------------------------------|--------------------------------------------------|
| Previous treatments for malaria | Not reported |
| Clinical setting | 2 primary care clinics |
| Country | Myanmar |
| Malaria endemicity | High endemicity |
| Malaria endemic species | *P. falciparum*, *P. vivax* |

#### Participants

| Sample size | 2585 |
| Age | Mean 10.9 years (SD not reported), range 0.1 to 94 years |
| Sex | 51.3% male, 48.7% female |
| Co-morbidities or pregnancy | Pregnant women were not included |

#### Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

#### Target condition and reference standard(s)

| Type(s) of malaria parasite tested for | Multi-species malaria |
| Reference standard test(s) used | Microscopy thick and thin smears. |
| Who performed the reference standard tests, and where | A laboratory technician performed the reference test. Location not reported, presumably on site |
| If microscopy was used, how many high power fields were looked at | At least 200 fields |
| How many observers or repeats were used | Slides were sent to a malaria research centre in Thailand, for external quality control |
| How were discrepancies between observers resolved | Not reported |

#### Index and comparator tests

| Commercial name of the test | SD Bioline Malaria Ag Pf/Pan 05FK60 (Standard Diagnostics, Kyonggi, Republic of Korea), |
| Parasite species the test is designed to detect | *P. falciparum* or mixed infection, non-falciparum species |
| Designated type | Type 3 |
| Batch numbers | Not reported |
| Transport and storage conditions | Not reported |
| Who performed the index test, and where | Not reported. As patients with fever or history of fever in the past 24 hours were immediately tested, presumably the RDTs were performed at the clinics |

#### Follow-up

Not applicable

#### Notes

| Source of funding | Source of funding not reported |

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**Table of Methodological Quality**

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review) 104
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
| Item                                      | Authors' judgement | Description                                                                                                                                 |
|-------------------------------------------|--------------------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?  
  All tests                                | Yes                | All non-pregnant patients visiting primary care clinics with fever or a history of fever in the prior 24 hours were included                |
| Acceptable reference standard?  
  All tests                                | No                 | It is reported that the program follows the WHO Malaria Microscopy Quality Assurance recommendation (reference provided). 1 technician read the slide on site. 900 (450 negative and 450 positive) of 2585 slides were sent to a malaria research unit in Thailand for external control |
| Partial verification avoided?  
  All tests                                | Yes                | All participants had their RDT results verified by microscopic reference test                                                              |
| Differential verification avoided?  
  All tests                                | Yes                | Microscopy was used for all samples.                                                                                                                                                                 |
| Incorporation avoided?  
  All tests                                | Yes                | Microscopy was used for all samples.                                                                                                                                                                 |
| Reference standard results blinded?  
  All tests                                | Yes                | The laboratory technician was not aware of the RDT result when examining the smear                                                          |
| Index test results blinded?  
  All tests                                | Yes                | RDT was performed immediately. The slide for microscopic evaluation was prepared after the RDT was performed                                 |
| Uninterpretable results reported?  
  All tests                                | Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| Withdrawals explained?  
  All tests                                | Yes                | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals |
Mekonnen 2010

| Clinical features and settings | Presenting signs and symptoms: Febrile, clinically suspected for malaria  
Previous treatment for malaria: No exclusions based on previous treatment, and no relevant data presented  
Clinical setting: Outpatient department of a health centre  
Country: Ethiopia (Jimma, South-West) - 300 km south-west of Addis Ababa, 1760 m above sea level  
Malaria endemicity: Not stated: transmission takes place throughout the year  
Malaria endemic species: P. falciparum and P. vivax |
|---|---|
| Participants | Sample size: 240  
Age: Eligible age range not stated. Actual age range of participants was 1 to 60 years, with a mean age of 25 years  
Sex: Both males and females eligible. 57.5% of the study participants were male, 42.5% female  
Co-morbidities and pregnancy: Not mentioned, either as an exclusion criteria or characteristic of the included participants  
Parasite density of microscopy positive cases: Not presented |
| Study design | Enrolment was prospective. The sampling method was not described. 1 RDT was evaluated |
| Target condition and reference standard(s) | Target condition: Malaria parasitaemia  
Reference standard: Microscopy thick and thin blood films  
Person(s) performing microscopy: Experienced malaria technicians  
Microscopy setting: Not stated  
Number of high power fields examined before declaring negative: 300  
Number of observer or repeats: Discordant results between RDTs and slides were repeated.  
Resolution of discrepancies between observers: Not described |
| Index and comparator tests | Commercial name of RDT: CareStart Malaria Pf/Pv Combo (Access Bio Inc, Monmouth Junction, New Jersey, USA)  
Parasite(s) designed to detect: P. falciparum and P. vivax  
Designated type: Type 5  
Batch numbers: Not stated  
Transport and storage conditions: Stored according to the guidelines of the manufacturer and quality of package desiccant was checked before use  
Person(s) performing RDT: Experienced malaria technicians  
RDT setting: Not stated |
| Follow-up | Not applicable |
| Notes | Source of funding: Received financial support from the School of Laboratory Studies of the Jimma University and the VLIR-IUC program between Flanders and Jimma University. Access Bio Ltd donated the CareStart Malaria Pf/Pv Combo test kit |

**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
|---|---|---|

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)  
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
| Question                                                                 | All tests | Description                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------------------|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                                                | Unclear   | All participants were attending a clinic with fever and suspected malaria, but the sampling method was not described                                                                                                                                                       |
| Acceptable reference standard?                                          | Yes       | Experienced technicians independently viewed 300 high power fields before declaring a slide negative. Discordant results was repeated independently                                                                                                               |
| Partial verification avoided?                                           | Yes       | All participants who received the index test also received the reference test                                                                                                                                                                                               |
| Differential verification avoided?                                      | Yes       | The same reference test was used regardless of the index test results                                                                                                                                                                                                     |
| Incorporation avoided?                                                  | Yes       | The index test does not form part of the reference standard.                                                                                                                                                                                                                  |
| Reference standard results blinded?                                     | Yes       | Blinding not described.                                                                                                                                                                                                                                                   |
| Index test results blinded?                                             | Yes       | “Results of the CareStart tests were determined prior to microscopic results with strict blinding to the microscopic examination of the blood film”                                                                                                                         |
| Uninterpretable results reported?                                       | Unclear   | The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis; therefore there were no exclusions due to invalid test results                                                                 |
| Withdrawals explained?                                                 | Yes       | The number of participants originally enrolled in the study was clearly stated, and corresponded to the number presented in the analysis: therefore there were no withdrawals                                                                                                      |
Presenting signs and symptoms: Not stated
Previous treatments for malaria: Not mentioned, either as an exclusion criteria or characteristic of included participants
Clinical setting: Health posts
Country: Venezuela
Malaria endemicity: “In 2007, the annual parasite index (API) was 68.4 cases/1000 inhabitants, but hot spots of higher malaria risk were seen in some indigenous ethnic groups.”
Malaria endemic species: *P. falciparum* and *P. vivax*

Sample size: 550
Age: Not mentioned either as an inclusion criteria or a characteristic of participants
Sex: Not mentioned either as an inclusion criteria or a characteristic of participants
Co-morbidities or pregnancy: Not mentioned either as an inclusion criteria or a characteristic of participants

No details of the enrolment and sampling method were reported. 1 RDT was evaluated

Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*
Reference standard test(s) used: microscopy
Who performed the reference standard tests, and where? Slides were examined by microscopists in health posts, then all positive and 10% of negative slides were re-examined by microscopists at the Regional Central Laboratory. Slides were then sent to the National Amazon Centre for Research and Control of Tropical Diseases in Puerto Ayacucho for re-examination by expert microscopists
If microscopy was used, how many high power fields were looked at? In the health posts and Regional Central Laboratory 200 fields of thick blood smears, and in the National Amazon Centre for Research and Control of Tropical Diseases the complete blood smear was read before being declared negative
How many observers or repeats were used? 3
How were discrepancies between observers resolved? Not reported

Commercial name of the test: OptiMAL-IT (Diamed AG, Cressier sur Morat, Switzerland)
Parasite species the test is designed to detect: *P. falciparum* or mixed infection, non- *falciparum* malaria species only
Designated type: Type 4
Batch numbers: Not stated
Transport and storage conditions: Samples were transported by messengers using boat, aeroplane, motorbike, bicycle and foot transportation, sometimes taking up to 4 weeks. Due to lack of refrigerators or due to electrical power cuts, or both, samples were often exposed to local ambient conditions (study average temperature of 26.9°C, with frequent peaks up to 40°C)
Who performed the index test, and where? Microscopists at health posts and expert microscopists at the Amazon Centre for Research and Control of Tropical Diseases in Puerto Ayacucho

Not applicable
| Item                              | Authors' judgement | Description                                                                                                                                 |
|----------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?         | Unclear            | No details of the characteristics of the participants were reported                                                                       |
| All tests                        |                    |                                                                                                                                             |
| Acceptable reference standard?   | Yes                | 3 microscopists read the slides at either 200 fields or the complete smear before declaring a test as negative                               |
| All tests                        |                    |                                                                                                                                             |
| Partial verification avoided?    | Yes                | “550 RDTs (OptiMAL-IT) and concomitant slides originating from the HPs of Atures municipality were received in the order of their arrival at the RCL in Puerto Ayacucho” |
| All tests                        |                    |                                                                                                                                             |
| Differential verification avoided?| Yes                | The same reference tests were used regardless of the index test results                                                                    |
| All tests                        |                    |                                                                                                                                             |
| Incorporation avoided?           | Yes                | The index test does not form part of the reference standard.                                                                                  |
| All tests                        |                    |                                                                                                                                             |
| Reference standard results blinded?| Yes                | Reported blinding.                                                                                                                         |
| All tests                        |                    |                                                                                                                                             |
| Index test results blinded?      | Yes                | Reported blinding.                                                                                                                         |
| All tests                        |                    |                                                                                                                                             |
| Uninterpretable results reported?| Unclear            | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals due to invalid results |
| All tests                        |                    |                                                                                                                                             |
| Withdrawals explained?           | Yes                | “36 tests had to be excluded because coding was lost during transport and/or because they could not be clearly allocated”                     |
| All tests                        |                    |                                                                                                                                             |
Clinical features and settings

**Presenting signs and symptoms:** Suspected malaria: fever, headache, fatigue, sweating/chills/rigors, vomiting, splenomegaly, myalgia and arthralgia, anaemia, hypoglycaemia

**Previous treatments for malaria:** Patients who had received anti-malarial drugs during the past 4 weeks were excluded

**Clinical setting:** Medical and paediatric out-patient departments of a health centre

**Country:** Ethiopia

**Malaria endemcity:** High endemcity

**Malaria endemic species:** *P. vivax* and *P. falciparum*

Participants

**Sample size:** 254

**Age:** Mean 21.4 (SD 14.76), range 0.4 to 75 years

**Sex:** 61% male, 39% female

**Co-morbidities or pregnancy:** Co-morbidities are not reported. However, critically ill patients who were unable to give blood were excluded from the study

Study design

Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT

Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*

**Reference standard test(s) used:** Microscopy thick and thin smears

**Who performed the reference standard tests, and where?** The tests were performed by an experienced laboratory technician at the health centre and an experienced microscopist at a university hospital laboratory

**If microscopy was used, how many high power fields were looked at?** 200 fields

**How many observers or repeats were used?** 2 observers

**How were discrepancies between observers resolved?** A third of discordant results, a third expert reader was used. This third reader’s results were considered final

Index and comparator tests

**Commercial name of the test:** CareStart™ Malaria HRP2/pLDH COMBO (Access Bio Inc., USA)

**Parasite species the test is designed to detect:** *P. falciparum* or mixed infection, non-falciparum species only

**Designated type:** Type 3

**Batch numbers:** Not reported

**Transport and storage conditions:** Not reported

**Who performed the index test, and where?** The index test was performed at the health centre. Information on the person who performed the test is not reported

Follow-up

**Not applicable**

Notes

**Source of funding:** Source of funding not reported. RDT kits were supplied by the North Gondar Zonal Health Bureau

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**Table of Methodological Quality**

| Item                        | Authors’ judgement | Description                                                      |
|-----------------------------|--------------------|------------------------------------------------------------------|
| Representative spectrum?    | Yes                | Subjects with suspected malaria symptoms were recruited (all symptoms reported) |
| All tests                   |                    |                                                                  |

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)  
Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.
### Acceptable reference standard?
| All tests | Yes | Microscopy evaluations were performed by 2 independent observers (200 fields). Discordant results were referred to a third observer. |

### Partial verification avoided?
| All tests | Yes | All participants receiving the index test had their diagnosis verified my microscopy. |

### Differential verification avoided?
| All tests | Yes | Microscopy was used as reference test for all samples. |

### Incorporation avoided?
| All tests | Yes | The reference standard for all samples was microscopy. |

### Reference standard results blinded?
| All tests | Yes | The microscopists were blinded to the RDT results. |

### Index test results blinded?
| All tests | Unclear | The same finger-prick blood sample used for microscopy was used to perform the index in parallel. |

### Uninterpretable results reported?
| All tests | Unclear | The number of participants enrolled in the study was clearly stated and corresponded to the number presented in the analysis; therefore there were no exclusions due to uninterpretable test results. |

### Withdrawals explained?
| All tests | Yes | The number of participants enrolled in the study was clearly stated and corresponded to the number included in the analysis; therefore there were no withdrawals. |

### Mohon 2012

**Clinical features and settings**
- **Presenting signs and symptoms:** Fever
- **Previous treatments for malaria:** Not reported
- **Clinical setting:** Upazila Health Complexes
- **Country:** Bangladesh
- **Malaria endemicity:** Hypo-endemicity
- **Malaria endemic species:** 95% *P. falciparum*

**Participants**
- **Sample size:** 372
- **Age:** Median 19.4, range 1.5 to 82 years
- **Sex:** 52.8 male, 47.2% female
- **Co-morbidities or pregnancy:** Co-morbidities and pregnancy not reported.
Study design
Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT.

Target condition and reference standard(s)
Type(s) of malaria parasite tested for: *P. falciparum, P. vivax*
Reference standard test(s) used: Microscopy thick and thin smears, nested PCR.
Who performed the reference standard tests, and where? Microscopy was performed by experienced microscopists on site and the icddr,b laboratory
If microscopy was used, how many high power fields were looked at? Microscopy was performed following the standard procedure. Details, not reported (reference provided)
How many observers or repeats were used? 2
How were discrepancies between observers resolved? Not reported

Index and comparator tests
Commercial name of the test: OnSite (Pf/Pan) (CTK Biotech Inc, USA)
Parasite species the test is designed to detect: *P. falciparum, non-falciparum, P. vivax*
Designated type: Type 3
Batch numbers: Not reported
Transport and storage conditions: Not reported
Who performed the index test, and where? The index test was performed at the icddr,b Parasitology Laboratory

Follow-up
Not applicable

Notes
Source of funding: International Centre for Diarrheal Research Bangladesh (icddr,b)

Table of Methodological Quality

| Item                           | Authors' judgement | Description                                                                                                                                 |
|--------------------------------|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?       | Unclear            | Febrile patients were recruited. However, patients with mixed infections and those with discordant microscopy/PCR results were excluded and the numbers excluded for these reasons are not stated |
| Acceptable reference standard? | Yes                | Microscopy was verified with PCR.                                                                                                                                                  |
| Partial verification avoided?  | Yes                | All participants that received the index test had their diagnosis verified by reference test                                                                                       |
| Differential verification avoided? | Yes              | PCR adjusted microscopy was used as the reference test                                                                                                                              |
| Incorporation avoided?         | Yes                | PCR adjusted microscopy was used as the reference test                                                                                                                              |
| Reference standard results blinded? | Yes               | Blinding not reported.                                                                                                                                                              |
Mohon 2012  (Continued)

| Question | Index test results blinded? | Blinding not reported. | Uninterpretable results reported? | No | The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any exclusions due to uninterpretable test results |
|----------|----------------------------|------------------------|-----------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------|
|          | All tests                  | Unclear                |                                    |    |                                                                                                                                  |
|          | Withdrawals explained?     | Unclear                |                                    |    | The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any withdrawals |
|          | All tests                  |                        |                                    |    |                                                                                                                                  |

Pattanasin 2003

Clinical features and settings

- Presenting signs and symptoms: Fever or history of fever and suspected diagnosis of uncomplicated malaria
- Previous treatment for malaria: No mention of previous treatment for malaria, either as an exclusion criteria or a characteristic of included participants
- Clinical setting: Not stated
- Country: Thailand (Mae Sod)
- Malaria endemicity: Not stated, peak transmission season
- Malaria endemic species: *P. falciparum* and *P. vivax*

Participants

- Sample size: 271
- Age: Children aged under 2 years were excluded. The study included participants aged 2 to 81 years; 71% were aged under 15 years
- Sex: Male: female ratio was 1.7:1
- Co-morbidities and pregnancy: Pregnant women were excluded
- Parasite density of microscopy positive cases: Not presented

Study design

- Enrolment was prospective. The sampling method was not described. 2 RDTs were evaluated, the vast majority of participants received both RDTs

Target condition and reference standard(s)

- Target condition: Malaria parasitaemia
- Reference standard: Microscopy thick and thin blood film
- Person(s) performing microscopy: Not stated
- Microscopy setting: Not stated
- Number of high power fields examined before declaring negative: Not stated
- Number of observer or repeats: Not stated
- Resolution of discrepancies between observers: Not applicable

Index and comparator tests

- Commercial name of RDT:
  - Paracheck-Pf (Orchid Biomedical Systems, Goa, India)
  - OptiMAL-IT (DiaMed, AG, Cressier, Switzerland)
- Parasite(s) designed to detect:
  - Paracheck-Pf - *P. falciparum*
• OptiMAL-IT - P. falciparum or mixed infection, non-falciparum species only

**Designated type:**
• Paracheck-Pf - Type 1
• OptiMAL-IT - Type 4

**Batch numbers:** Not stated

**Transport and storage conditions:** Kept at room temperature and opened just before performing the test to avoid humidity

**Person(s) performing RDT:** Not stated

**RDT setting:** Not stated

**Follow-up**

Not applicable

**Notes**

Source of funding: Not stated

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### Table of Methodological Quality

| Item                        | Authors' judgement | Description                                                                 |
|-----------------------------|--------------------|----------------------------------------------------------------------------|
| Representative spectrum?    | Unclear            | All participants had a fever and suspected malaria, but the exact clinical setting and the sampling method were not described |
| All tests                   |                    |                                                                            |
| Acceptable reference standard? | Unclear       | No details of the microscopy process were given.                             |
| All tests                   |                    |                                                                            |
| Partial verification avoided? | Yes             | All participants who received the index test also received the reference test |
| All tests                   |                    |                                                                            |
| Differential verification avoided? | Yes       | The same reference test was used regardless of the index test results     |
| All tests                   |                    |                                                                            |
| Incorporation avoided?      | Yes                | The index test does not form part of the reference standard.                |
| All tests                   |                    |                                                                            |
| Reference standard results blinded? | Unclear   | Blinding not described.                                                     |
| All tests                   |                    |                                                                            |
| Index test results blinded? | Yes                | Test results were recorded without reference to the microscopy results     |
| All tests                   |                    |                                                                            |
| Uninterpretable results reported? | Yes     | Doubtful and invalid results were reported (5 of 271).                     |
| All tests                   |                    |                                                                            |
| Withdrawals explained?      | Unclear            | Almost all participants were reported to receive the same index and reference tests (271 participants in total, 266 received OptiMAL, 269 received Paracheck-Pf); the numbers presented in the analysis correspond |
| All tests                   |                    |                                                                            |
### Rakotonirina 2008

| Clinical features and settings | Presenting signs and symptoms: Fever over 37.5°C or history of fever in the previous 24 hours  
Previous treatment for malaria: Participants with recent antimalarial use were not excluded from the study; 34% of participants declared antimalarial use  
Clinical setting: 2 primary health centres  
Country: Madagascar (Tsiroanomandidy on the west foothill areas of the Highlands)  
Malaria endemicity: Low and predominantly seasonal  
Malaria endemic species: *P. falciparum* (80%) and *P. vivax* |
| Participants | Sample size: 313  
Age: All age groups were eligible for inclusion; the actual age range of the included participants was 6 months to 79 years (median age 10 years)  
Sex: Male: female ratio was 1.2:1  
Co-morbidities and pregnancy: Pregnant women were excluded, as were people with signs of severe or complicated malaria  
Parasite density of microscopy positive cases: Range 32 to 52,750 parasites per µL, mean 4104, SD 7894 |
| Study design | Enrolment was consecutive and prospective. 2 RDTs were evaluated, all participants received both RDTs |
| Target condition and reference standard(s) | Target condition: Malaria parasitaemia  
Reference standard: PCR |
| Index and comparator tests | Commercial name of RDT:  
- OptiMAL-IT (DiaMed, AG, Cressier, Switzerland)  
- PALUTOP  
Parasite(s) designed to detect:  
- OptiMAL-IT - *P. falciparum* or mixed infection, non-falciparum species only  
- PALUTOP - *P. falciparum*, *P. vivax* and other malaria types  
Designated type:  
- OptiMAL-IT - Type 4  
- PALUTOP - Type 6  
Batch numbers:  
- OptiMAL-IT - 46110.85.01  
- PALUTOP - 91014  
Transport and storage conditions: Transported and maintained at the study sites (primary health centres) at room temperature and opened just before use to avoid humidity damage  
Person(s) performing RDT: Trained technician  
RDT setting: Primary health centres |
| Follow-up | Not applicable |
| Notes | Source of funding: Global Fund Project for Madagascar, Round 3 |

### Table of Methodological Quality
### Rakotonirina 2008

(Continued)

| Item                           | Authors’ judgement | Description                                                                                                                                 |
|--------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?       | Yes                | Participants were a consecutive sample of patients attending primary health centres with fever or history of fever in the previous 24 hours.     |
| Acceptable reference standard? | Yes                | Reference standard was PCR.                                                                                                               |
| Partial verification avoided?  | Yes                | All participants who received the index test also received the reference test.                                                              |
| Differential verification avoided? | Yes        | The same reference test was used regardless of the index test results.                                                                       |
| Incorporation avoided?         | Yes                | The index test does not form part of the reference standard.                                                                                |
| Reference standard results blinded? | Yes            | Stated that the PCR operator was blind to the results of the other tests performed.                                                        |
| Index test results blinded?    | Yes                | Stated that the test readers were blind to the results of the other tests performed.                                                        |
| Uninterpretable results reported? | Yes            | There were no test failures with either RDT.                                                                                               |
| Withdrawals explained?         | Yes                | The number of participants enrolled in the study is clearly stated and corresponds to the number presented in the analysis.                 |

### Ratsimbasoa 2007

**Clinical features and settings**

- **Presenting signs and symptoms**: Fever over 37.5°C or history of fever in the previous 24 hours, with typical malaria symptoms. Patients with signs of severe or complicated malaria were excluded.
- **Previous treatment for malaria**: Participants with recent antimalarial use were not excluded from the study; 17% of participants reported antimalarial use.
- **Clinical setting**: Primary health centres.
- **Country**: Madagascar. Rural areas of Mahasolo (western foothills areas of the highlands) and Saharevo (eastern foothills areas of the highlands).
- **Malaria endemicity**: Low and predominantly seasonal in both areas.
- **Malaria endemic species**: Predominantly *P. falciparum*; some *P. vivax*.

**Participants**

- **Sample size**: 194
- **Age**: All groups eligible for inclusion not stated; actual age range of the included participants was 1 to 79 years (mean age 15.2 years). 12.9% were under 5 years of age.
Sex: Male: female ratio was 0.98:1

Co-morbidities and pregnancy: Pregnant women were excluded, as were people with signs of severe or complicated malaria

Parasite density of microscopy positive cases: Range 16 to 233,600 parasites per µL, mean 6564, SD 26,553

Study design
Enrolment was prospective. The sampling method was not described. 2 RDTs were evaluated, all participants received both RDTs

Target condition and reference standard(s)
Target condition: Malaria parasitaemia
Reference standard: Microscopy thick and thin blood films
Person(s) performing microscopy: An experienced technician
Microscopy setting: Not stated
Number of high power fields examined before declaring negative: 200
Number of observer or repeats: 1
Resolution of discrepancies between observers: Not applicable

Index and comparator tests
Commerical name of RDT:
- CareStart Malaria Pf/Pan (Access Bio Inc., Monmouth Junction, NJ)
- SD Malaria Antigen Bioline Pf/Pan (Standard Diagnostics, Suwon City, South Korea)
- OptiMAL-IT (DiaMed, AG, Cressier, Switzerland)
Parasite(s) designed to detect: *P. falciparum* or mixed infection, non-falciparum species only
Designated type: Type 4
Batch numbers:
- CareStart Malaria - J25IL, J35IL, J45IL, J55IL
- SD Malaria Antigen Bioline - T5001, T5002, T5003, T5004
- OptiMAL-IT - 46110.73.01, 46110.74.01, 46110.75.01

Transport and storage conditions: Transported and maintained at the study sites (primary health centres) at room temperature and opened just before use to avoid humidity damage
Person(s) performing RDT: A technician
RDT setting: Not stated

Follow-up
Not applicable

Notes
Source of funding: Global Fund Project for Madagascar, Round 3. The manufacturers supplied the test kits

Table of Methodological Quality

| Item                      | Authors’ judgement | Description |
|---------------------------|--------------------|-------------|
| Representative spectrum?  | Unclear            | All participants were attending primary health centres with fever and symptoms of malaria, but the sampling method was not described |
| All tests                 |                    |             |
### Acceptable reference standard?

| All tests | No | An expert technician viewed 200 high power fields before declaring a slide negative; however their findings were not verified by a second independent reader |

### Partial verification avoided?

| All tests | Yes | All participants who received the index test also received the reference test |

### Differential verification avoided?

| All tests | Yes | The same reference test was used regardless of the index test results |

### Incorporation avoided?

| All tests | Yes | The index test does not form part of the reference standard. |

### Reference standard results blinded?

| All tests | Yes | “Analyzed without reference to the RDT results”. |

### Index test results blinded?

| All tests | Yes | The RDTs were undertaken before the microscopy. |

### Uninterpretable results reported?

| All tests | Unclear | The number recruited into the study was clearly stated, and corresponded with the number included in the analysis |

### Withdrawals explained?

| All tests | Yes | The number recruited into the study was clearly stated, and corresponded with the number included in the analysis |

### Ratsimbasoa 2008

#### Clinical features and settings

**Presenting signs and symptoms:** Fever or fever in the previous 24 hours with typical malaria symptoms  
**Previous treatment for malaria:** Participants with recent antimalarial use were not excluded from the study; 13% of participants declared antimalarial use  
**Clinical setting:** Primary Health Centre  
**Country:** Madagascar (Ampasimpotsy, Central Highlands)  
**Malaria endemicity:** Transmission is low and predominantly seasonal. This study was carried out in the low season  
**Malaria endemic species:** *P. falciparum* (approximately 75%) and *P. vivax*

#### Participants

**Sample size:** 200  
**Age:** Eligible age range not stated; actual age range of the included participants was 6 months to 73 years (40% under 5 years, 26.5% 5 to 15 years)  
**Sex:** Male: female ratio was 1.2:1  
**Co-morbidities and pregnancy:** Pregnant women were excluded, as were people with signs of severe or complicated malaria  
**Parasite density of microscopy positive cases:** Range 16 to 285,000 parasites per µL, mean 16,757, SD 42,631
**Study design**

Enrolment was prospective. The sampling method was not described. 2 RDTs were evaluated, all participants received both RDTs.

**Target condition and reference standard(s)**

**Target condition:** Malaria parasitaemia  
**Reference standard:** PCR

**Index and comparator tests**

**Commerical name of RDT:**  
- SD Bioline Malaria Ag Pf (Standard Diagnostics Inc., Suwon City, South Korea)  
- SD Bioline Malaria Ag Pf/Pan (Standard Diagnostics Inc., Suwon City, South Korea)

**Parasite(s) designed to detect:**  
- SD Bioline Malaria Ag Pf - *P. falciparum*  
- SD Bioline Malaria Ag Pf/Pan - *P. falciparum* or mixed infection, non-falciparum species only

**Designated type:**  
- SD Bioline Malaria Ag Pf - Type 1  
- SD Bioline Malaria Ag Pf/Pan - Type 3

**Batch numbers:**  
- SD Bioline Malaria Ag Pf - 05FK50  
- SD Bioline Malaria Ag Pf/Pan - 05FK60

**Transport and storage conditions:** All tests were kept at room temperature and opened just before use to avoid humidity damage

**Person(s) performing RDT:** Not stated  
**RDT setting:** Not stated

**Follow-up**

Not applicable

**Notes**

**Source of funding:** Kozone, representing Standard Diagnostics Inc in Madagascar

**Table of Methodological Quality**

| Item                                      | Authors' judgement | Description                                                                 |
|-------------------------------------------|--------------------|------------------------------------------------------------------------------|
| Representative spectrum?                 | Unclear            | Participants were all attending a health centre with fever and typical symptoms of malaria, but the sampling method was not described |
| All tests                                 |                    |                                                                              |
| Acceptable reference standard?            | Yes                | The reference standard was PCR.                                              |
| All tests                                 |                    |                                                                              |
| Partial verification avoided?             | Yes                | All participants who received the index test also received the reference test |
| All tests                                 |                    |                                                                              |
| Differential verification avoided?        | Yes                | The same reference test was used regardless of the index test results       |
| All tests                                 |                    |                                                                              |
| Incorporation avoided?                   | Yes                | The index test does not form part of the reference standard.                 |
| All tests                                 |                    |                                                                              |
| Reference standard results blinded? | Yes | PCR was carried out by technicians blind to the results of RDT testing |
|-----------------------------------|-----|---------------------------------------------------------------------|
| All tests                         |     |                                                                      |
| Index test results blinded?       | Yes | RDTs were undertaken before the results of PCR were known           |
| All tests                         |     |                                                                      |
| Uninterpretable results reported? | Yes | Uninterpretable results are reported and excluded from the analysis. There were 2 invalid results for Bioline Pf and 1 for Bioline Pf/Pan |
| All tests                         |     |                                                                      |
| Withdrawals explained?            | No  | There was 1 participant missing from the analysis from Bioline Pf/Pan, with no explanation |
| All tests                         |     |                                                                      |

**Samane 2010**

### Clinical features and settings

**Presenting signs and symptoms:** Suspected malaria with symptoms including fever or chills of several days, or both

**Previous treatments for malaria:** Not mentioned, either as an exclusion criteria or characteristic of included participants

**Clinical setting:** Health centres

**Country:** Iran

**Malaria endemicity:** Not stated

**Malaria endemic species:** Not stated

### Participants

**Sample size:** 250

**Age:** Not mentioned either as an inclusion criteria or a characteristic of participants

**Sex:** Not mentioned either as an inclusion criteria or a characteristic of participants

**Co-morbidities or pregnancy:** Not mentioned either as an inclusion criteria or a characteristic of participants

### Study design

Enrolment was prospective. The sampling method was not described. 1 RDT was evaluated

### Target condition and reference standard(s)

**Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*

**Reference standard test(s) used:** Microscopy

**Who performed the reference standard tests, and where?** Experienced microscopists performed the test, it is not stated where this was done

**If microscopy was used, how many high power fields were looked at?** Not stated

**How many observers or repeats were used?** 2

**How were discrepancies between observers resolved?** Not stated

### Index and comparator tests

**Commercial name of the test:** BIOTEC Malaria Pf/Pf Rapid Device

**Parasite species the test is designed to detect:** *P. falciparum* and *P. vivax*

**Designated type:** Other type. HRP-2 for *P. falciparum* and pLDH for *P. vivax.*

**Batch numbers:** Not stated

**Transport and storage conditions:** Not reported
Table of Methodological Quality

| Item                              | Authors’ judgement | Description                                                                 |
|-----------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum?          | Unclear            | Characteristics of participants not adequately described, although all had symptoms of malaria |
| All tests                         |                    |                                                                             |
| Acceptable reference standard?    | Unclear            | 2 independent microscopists viewed the slides, but the number of fields viewed was not reported |
| All tests                         |                    |                                                                             |
| Partial verification avoided?     | Yes                | All participants who received the index test also received the reference tests |
| All tests                         |                    |                                                                             |
| Differential verification avoided?| Yes                | The same reference tests were used regardless of the index test results    |
| All tests                         |                    |                                                                             |
| Incorporation avoided?            | Yes                | The index test does not form part of the reference test.                    |
| All tests                         |                    |                                                                             |
| Reference standard results blinded?| Yes               | Reported that the tests were read blindly.                                  |
| All tests                         |                    |                                                                             |
| Index test results blinded?       | Yes                | Reported that the tests were read blindly.                                  |
| All tests                         |                    |                                                                             |
| Uninterpretable results reported? | No                 | Number enrolled in the study was explicitly stated but did not correspond to the number presented in the analysis - 250 patients were enrolled but 276 were included in the analysis |
| All tests                         |                    |                                                                             |
| Withdrawals explained?            | Unclear            | Number enrolled in the study was explicitly stated but did not correspond to the number presented in the analysis - 250 patients were enrolled but 276 were included in the analysis |
| All tests                         |                    |                                                                             |
**Clinical features and settings**

- **Presenting signs and symptoms:** Fever with oral temperature 100 °F or more or with convincing history of fever
- **Previous treatments for malaria:** "Patients taking anti-malarial drugs for current illness or providing history of anti-malarial therapy within previous four weeks or taking anti-malarial prophylaxis were excluded from the study"
- **Clinical setting:** Sick bay of 37 Rifle Battalion Headquarters
- **Country:** Bangladesh
- **Malaria endemicity:** "Malaria endemic zone"
- **Malaria endemic species:** Not stated

**Participants**

- **Sample size:** 271
- **Age:** Ranged from 18 years to 57 years
- **Sex:** Male
- **Co-morbidities or pregnancy:** Not mentioned either as an inclusion criteria or a characteristic of participants

**Study design**

- **Were participants consecutively enrolled in the study?:** Yes
- **Were they enrolled prospectively?:** Yes
- **If the study evaluated more than one RDT, how were tests allocated to individuals, or did each individual receive all the tests?** 1 RDT was evaluated

**Target condition and reference standard(s)**

- **Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax* malaria
- **Reference standard test(s) used:** Microscopy thick and thin blood films
- **Who performed the reference standard tests, and where?** Experienced microscopists at Armed Forces Medical College in Dhaka examined the slides
- **If microscopy was used, how many high power fields were looked at?** 200
- **How many observers or repeats were used?** 1
- **How were discrepancies between observers resolved?** Only 1 microscopist read each slide

**Index and comparator tests**

- **Commercial name of the test:** MALARIGEN MALARIA Pf/Pv Antigen Rapid Test (Biotest Diagnostic Corp., Denville, NJ, USA)
- **Parasite species the test is designed to detect:** *P. falciparum*, *P. vivax* malaria
- **Designated type:** Unclear, HRP-2 antigen of *P. falciparum* and unspecified monoclonal antibodies for detection of non-falciparum malarial parasites
- **Batch numbers:** Not stated
- **Transport and storage conditions:** Not stated
- **Who performed the index test, and where?** Experienced microscopists at Armed Forces Medical College in Dhaka examined the RDT kits

**Follow-up**

- **Not applicable**

**Notes**

- **Source of funding:** Not stated

**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
|------|---------------------|-------------|

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Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)

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## Selimuzzaman 2010 (Continued)

| Test Type | All Tests | Yes/No | Notes |
|-----------|-----------|--------|-------|
| Representative spectrum? | | Yes | Participants were a consecutive series of patients with clinical signs and symptoms of malaria |
| Acceptable reference standard? | | No | One microscopist read each slide. |
| Partial verification avoided? | | Yes | All participants who received the index test also received the reference tests |
| Differential verification avoided? | | Yes | The same reference test was used regardless of the index test results |
| Incorporation avoided? | | Yes | The index test does not form part of the reference standards |
| Reference standard results blinded? | | Unclear | Described as a single blinded study, but no further details reported |
| Index test results blinded? | | Unclear | Described as a single blinded study, but no further details reported |
| Uninterpretable results reported? | | Yes | “Three out of 271 (1.11%) cases did not demonstrate control band or become positive only after a long time lag and were excluded from the study. Thin blood films of 6 patients (2.21%) were marked by the microscopist as poor quality and were excluded from the study.” |
| Withdrawals explained? | | Yes | The number of participants enrolled in the study is clearly stated and corresponds to the number presented in the analysis minus the number reported to have invalid test results or incomplete data |

## Sharew 2009

| Test Type | All Tests | Notes |
|-----------|-----------|-------|
| Clinical features and settings | | Presenting signs and symptoms: Febrile patients, clinically suspected for malaria Previous treatment for malaria: No exclusions based on previous treatment. Information on previous treatment collected, but actual data not provided Clinical setting: Outpatient departments of 2 health centres Country: Ethiopia (Southern - Wondo Genet) Malaria endemicity: Takes place throughout the year Malaria endemic species: *P. falciparum* and *P. vivax* |
| Participants | | Sample size: 668 Age: All age groups eligible. Actual age range 6 months to 75 years |
Sharew 2009  (Continued)

| Study design | Enrolment was consecutive and prospective. 2 different RDTs were evaluated, and each participant received both tests |
| --- | --- |
| Target condition and reference standard(s) | **Target condition**: Malaria parasitaemia  
**Reference standard**: Microscopy thick and thin blood films  
**Who performed the reference standard tests, and where?** Experienced malaria technicians. The microscopy setting was not stated, but in the Wondo Genet area  
**If microscopy was used, how many high power fields were looked at?** 100  
**How many observers or repeats were used?** 2 independent technicians, also checked by the team leader  
**How were discrepancies between observers resolved?** All discordant results between microscopy and RDTs were repeated |
| Index and comparator tests | **Commercial name of RDT:**  
- Paracheck Pf (Orchid Biomedical Systems, Goa, India)  
- CareStart Malaria Pf/Pv Combo test (Access Bio INc, New Jersey, USA)  
**Parasite(s) designed to detect:** *P. falciparum*  
- Paracheck Pf - *P. falciparum*  
- CareStart Malaria Pf/Pv Combo test - *P. falciparum, P. vivax* or mixed infection  
**Designated type:**  
- Paracheck Pf - Type 1  
- CareStart Malaria Pf/Pv Combo test - Type 5  
**Batch numbers:** Not stated  
**Transport and storage conditions:** As per the instructions of the manufacturer  
**Person(s) performing RDT:** Not stated  
**RDT setting:** 2 health centres |
| Follow-up | Not applicable |
| Notes | **Source of funding:** School of Graduate Studies of the Addis Adaba University through the Graduate Programme in Tropical and Infectious Diseases, Akilu Lemma Institute of Pathobiology and from the Federal Ministry of Health of Ethiopia. Federal Ministry of Health of Ethiopia and Access Bio Inc donated the test kits |

**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
| --- | --- | --- |
| Representative spectrum? All tests | Yes | Participants were a consecutive sample of febrile patients attending health centres with suspected malaria |
### Sharew 2009  (Continued)

| Acceptable reference standard? All tests | Yes | 2 experienced microscopists independently viewed 100 high power fields before declaring a slide negative |
|-----------------------------------------|-----|--------------------------------------------------------------------------------------------------|
| Partial verification avoided? All tests  | Yes | All participants who received the index test also received the reference test |
| Differential verification avoided? All tests | Yes | The same reference test was used regardless of the index test results |
| Incorporation avoided? All tests        | Yes | The index test does not form part of the reference standard. |
| Reference standard results blinded? All tests | Unclear | Not described. |
| Index test results blinded? All tests    | Yes | Strict blinding with the results available before microscopy reported |
| Uninterpretable results reported? All tests | Yes | If a test was un-interpretable then it was repeated. |
| Withdrawals explained? All tests        | Yes | The number of participants enrolled in the study was clearly stated and corresponds to the number included in the analysis; therefore there were no withdrawals |

### Singh 2000a

**Clinical features and settings**
- **Presenting signs and symptoms:** Fever suspected to be malaria
- **Previous treatment for malaria:** There were no exclusions based on previous treatment, and no information presented; this was an outbreak in a rural area
- **Clinical setting:** Mobile field laboratory
- **Country:** India (forest villages in Chhindwara, central India)
- **Malaria endemicity:** Outbreak situation
- **Malaria endemic species:** *P. falciparum* and *P. vivax*

**Participants**
- **Sample size:** 344
- **Age:** All age groups eligible. Actual age range 6 months to 65 years
- **Sex:** Both males and females eligible. Actual proportions of males and females in the participant population not stated
- **Co-morbidities and pregnancy:** No exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented
- **Parasite density of microscopy positive cases:** Not presented

**Study design**
- Enrolment was consecutive and prospective. 1 RDT was evaluated
Target condition and reference standard(s)

**Target condition:** Malaria parasitaemia  
**Reference standard:** Microscopy thick blood film  
**Who performed the reference standard tests, and where?** Experienced microscopist for all slides; expert microscopist for re-examined slides. Setting was a mobile field laboratory for all slides; Malaria Research Centre at Jabalur for re-examined slides  
**If microscopy was used, how many high power fields were looked at?** Not stated. However, 200 white blood cells were counted as an alternative indicator; or 500 WBCs for slides that were re-examined  
**How many observers or repeats were used?** 1, but negative blood smears were re-examined if the patient was having severe symptoms, the corresponding RDT result was positive or if *P. vivax* was diagnosed  
**How were discrepancies between observers resolved?** Not described, most likely accepted the findings of second microscopist

Index and comparator tests

**Commercial name of RDT:** ICT Malaria Pf/Pv (AMRAD, Australia)  
**Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum species only  
**Designated type:** Type 2  
**Batch numbers:** Not stated  
**Transport and storage conditions:** Not described  
**Person(s) performing RDT:** Field laboratory assistants  
**RDT setting:** Mobile field laboratory

Follow-up

Not applicable

Notes

**Source of funding:** Becton Dickinson provided financial support and supplied the RDTs free of charge

### Table of Methodological Quality

| Item                              | Authors’ judgement | Description                                                                 |
|----------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum? All tests | Yes                | All participants were attending an ambulatory setting with fever suspected to be malaria, and enrolment was consecutive |
| Acceptable reference standard? All tests | No                | Microscopy was undertaken by 1 microscopist only; and the number of high power fields viewed was unclear (200 white blood cells) |
| Partial verification avoided? All tests | Yes               | All participants who received the index test also received the reference test |
| Differential verification avoided? All tests | Yes               | The same reference test was used regardless of the index test results |
Singh 2000a  (Continued)

| Incorporation avoided? | Yes | The index test does not form part of the reference standard. |
|------------------------|-----|----------------------------------------------------------------|
| Reference standard results blinded? | Yes | “Blood films were examined...without reference to the results of ICT” |
| Index test results blinded? | Yes | “All specimens were tested...who were blinded to the results of the blood smear tests” |
| Uninterpretable results reported? | Unclear | The numbers of participants originally enrolled in the study was clearly stated and the numbers presented in the analysis correspond; therefore there were no exclusions due to uninterpretable test results |
| Withdrawals explained? | Yes | The numbers of participants originally enrolled in the study was clearly stated and the numbers presented in the analysis correspond; therefore there were no withdrawals |

Singh 2003

| Clinical features and settings | Presenting signs and symptoms: Fever or history of fever Previous treatment for malaria: No explicit exclusions based on previous treatment, and no data reported Clinical setting: Hospital malaria clinic Country: India, Jabalpur Malaria endemicity: Not stated Malaria endemic species: *P. falciparum* and *P. vivax* in roughly equal proportions |
|-------------------------------|-----------------------------------------------------------------------------------|
| Participants | Sample size: 80 Age: All age groups eligible. Adults and children included; mean age 27.7 (SD 16.42) for males and 29 (SD 12.8) for females Sex: Both males and females eligible; included 28 males and 18 females Co-morbidities and pregnancy: No explicit exclusion criteria based on co-morbidities or pregnancy. No details of the frequency of these conditions in the participant population is presented Parasite density of microscopy positive cases: Range 40 to 370,574 parasites per µL for *P. falciparum* and 318 to 9970 for *P. vivax* |
| Study design | Enrolment was prospective. The sampling method was not described. Only 1 RDT was evaluated |
| Target condition and reference standard(s) | Target condition: Malaria parasitaemia Reference standard: Microscopy thick blood films Who performed the reference standard tests, and where? Not stated. Setting was a hospital laboratory |
If microscopy was used, how many high power fields were looked at? Not stated

How many observers or repeats were used? If the results of the OptiMAL conflicted with that of microscopy for any sample, the blood smear was re-examined by a different technician

How were discrepancies between observers resolved? If the re-examination of discordant results gave a different result to the first examination, the second results was confirmed by yet another technician

Index and comparator tests

Commercial name of RDT: OptiMAL
Parasite(s) designed to detect: P. falciparum or mixed infection, non-falciparum species only
Designated type: Type 4
Batch numbers: Not stated
Transport and storage conditions: Not described
Person(s) performing RDT: A technician
RDT setting: Hospital clinic or laboratory

Follow-up

Notes

Source of funding: Not stated.

Table of Methodological Quality

| Item                             | Authors’ judgement | Description                                                                                                                                 |
|----------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum? All tests | Unclear            | Participants were all attending a clinic with fever or history of fever, but the sampling method was not described                             |
| Acceptable reference standard? All tests | Unclear            | Discordant results between RDT and microscopy were re-examined; however the number of high power fields viewed before declaring a sample negative was not stated |
| Partial verification avoided? All tests | Yes                | All participants who received the index test also received the reference test                                                               |
| Differential verification avoided? All tests | Yes                | The same reference test was used regardless of the index test results                                                                       |
| Incorporation avoided? All tests | Yes                | The index test does not form part of the reference standard.                                                                                   |
| Reference standard results blinded? All tests | Unclear            | Blinding not described.                                                                                                                        |
| Index test results blinded? All tests | Yes                | Technician were blinded to the results of the blood smear examination                                                                       |
Singh 2003  

| Uninterpretable results reported? All tests | Unclear | The numbers of participants originally enrolled in the study was clearly stated and the numbers presented in the analysis correspond; therefore there were no exclusions due to uninterpretable test results |
|-------------------------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------|
| Withdrawals explained? All tests | Yes | The numbers of participants originally enrolled in the study was clearly stated and the numbers presented in the analysis correspond; therefore there were no withdrawals |

Singh 2010

| Clinical features and settings | Presenting signs and symptoms: Clinical suspicion of malaria  
Previous treatments for malaria: Patients were excluded due to recent anti-malarial intake  
Clinical setting: Field clinic  
Country: India  
Malaria endemicity:  
Malaria endemic species: *P. falciparum* and *P. vivax* |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| Participants | Sample size: 409  
Age: All ages were included. Mean age was 15 (SD 14).  
Sex: Both sexes were included, ratio was not reported.  
Co-morbidities or pregnancy: Pregnant women were excluded from participating. Co-morbidities not mentioned either as an inclusion criteria or a characteristic of participants |
| Study design | Enrolment was prospective and consecutive. 5 RDTs were evaluated; each participant received all the tests |
| Target condition and reference standard(s) | Type(s) of malaria parasite tested for: *P. falciparum* and *P. vivax*  
Reference standard test(s) used: Microscopy and PCR  
Who performed the reference standard tests, and where? Microscopy was conducted by an experienced microscopist in the laboratory. PCR was also performed in the laboratory, by an independent research assistant  
If microscopy was used, how many high power fields were looked at? 100  
How many observers or repeats were used? 1  
How were discrepancies between observers resolved? “All negative slides that test positive on the RDT/PCR or all positive slides that test negative on the RDT/PCR were re-examined by another expert technician blinded to the results of microscopy, RDT/PCR and clinical status of the patients.” |
| Index and comparator tests | Commercial name of the test:  
• Parascreen Device (rapid test for malaria Pan/Pf) (Zephyr Biomedicals Goa)  
• Falcivax Device (rapid test for malaria Pv/Pf) (Zephyr Biomedicals Goa)  
• Malascan Device (rapid test for malaria Pf/Pan) (Zephyr Biomedicals Goa),  
• ParaHIT Total (rapid test for Pf & Pan Malaria species) (SPAN Diagnostics Ltd, Surat) |
Singh 2010  (Continued)

- First Response Malaria Antigen Combo Card test (pLDH/HRP2) (Premier medical corporation Mumbai)

**Parasite species the test is designed to detect:**
- Parascreen - malaria Pan/Pf
- Falcivax - malaria Pv/Pf
- Malascan - malaria Pf/Pan
- ParaHIT Total - Pf & Pan Malaria species
- First Response Malaria Antigen Combo Card test - pLDH/HRP2

**Designated type:**
- Parascreen - Type 3
- Falcivax - Type 5
- Malascan - Type 2
- ParaHIT Total - Type 2
- First Response Malaria Antigen Combo Card test - Type 3

**Batch numbers:** Not stated

**Transport and storage conditions:** "RDTs were stored at 25°C on receipt in the study sites, then allocated to separate groups for storage at 35°C & 45°C for 90 days, at 60°C for 48 hours, and at -10°C for 60 minutes before testing. At the start of the study, the incubators were stabilized at the required temperature for three days before the RDTs to be tested were placed inside. RDTs were removed from storage to reach room temperature for 2 hours before testing and comparisons were made with control RDTs kept at 25°C until use and with microscopy."

**Who performed the index test, and where?** 2 research assistants tested in the RCTs in field in 10 villages of Satanwada Primary Health Centre

**Follow-up**
- Not applicable

**Notes**
- **Source of funding:** WHO Country Office, New Delhi, India

**Table of Methodological Quality**

| Item                          | Authors’ judgement | Description                                                                 |
|-------------------------------|--------------------|-----------------------------------------------------------------------------|
| Representative spectrum?      | Yes                | Participants were a consecutive series of patients attending clinics with clinical signs and symptoms of malaria |
| All tests                     |                    |                                                                             |
| Acceptable reference standard?| No                 | Only 1 microscopist used, except in cases of discordant results between microscopy and RDT |
| All tests                     |                    |                                                                             |
| Partial verification avoided? | Yes                | All participants who received the index test also received the reference test |
| All tests                     |                    |                                                                             |
| Differential verification avoided? | Yes             | The same reference tests were used regardless of the index test results     |
| All tests                     |                    |                                                                             |
| Incorporation avoided?        | Yes                | The index test does not form part of the reference standards                |
| All tests                     |                    |                                                                             |
Singh 2010  (Continued)

| Question                                                                 | All tests | Included references |
|--------------------------------------------------------------------------|-----------|---------------------|
| Reference standard results blinded?                                      | Yes       | Reported that the tests were read blindly. |
| Index test results blinded?                                              | Yes       | Reported that the tests were read blindly. |
| Uninterpretable results reported?                                        | Unclear   | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore no withdrawals due to invalid results |
| Withdrawals explained?                                                   | Yes       | 37 patients (9%) were excluded as not fulfilling the study enrolment criteria due to recent anti-malarial intake |

Tjitra 1999

Clinical features and settings

- **Presenting signs and symptoms**: Symptomatic with a presumptive clinical diagnosis of malaria: fever or history of fever in the last 24 hours and no other obvious cause of fever
- **Previous treatment for malaria**: Prior use of antimalarials was not an exclusion criteria. Approximately half of the participants reported use of antimalarials within the previous 4 weeks
- **Clinical setting**: Primary health centre
- **Country**: Indonesia (Laratama subdistrict, West Sumba, East Nusa Tenggara Province, Eastern Indonesia)
- **Malaria endemicity**: Infection rate in children 0 to 9 years of 5.1%
- **Malaria endemic species**: *P. falciparum* and *P. vivax*

Participants

- **Sample size**: 560
- **Age**: All ages eligible. Actual age range of the participants 0 to 80 years
- **Sex**: Males and females eligible; 289 males and 271 females included
- **Co-morbidities**: Not mentioned either as an exclusion criteria or a characteristic of the included participants
- **Parasite density of microscopy positive cases**: *P. vivax* mean 7157 parasites per µL

Study design

Enrolment was prospective. The sampling method was not described. 1 RDT was tested

Target condition and reference standard(s)

- **Target condition**: Malaria parasitaemia
- **Reference standard**: Microscopy thick and thin blood smears
- **Who performed the reference standard tests, and where?**: Expert microscopists with over 20 years experience each. The setting was one local (exact setting not stated); cross-checking was done in Darwin, Australia
- **If microscopy was used, how many high power fields were looked at?**: at least 100 for all slides, at least 200 for those cross-checked
- **How many observers or repeats were used?**: 1 observer for the majority of slides; discordant results between microscopy and RDT and 20% of slides with concordant results were cross-checked by a 2nd microscopist, blind to the results of 1st microscopy and RDT
Tjitra 1999  (Continued)

| Item                                      | Authors’ judgement | Description                                                                                                                                 |
|-------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| How were discrepancies between observers resolved? | Not described     |                                                                                                                                            |
| Index and comparator tests                | Commerical name of RDT: ICT Malaria Pf/Pv | Parasite(s) designed to detect: *P. falciparum* or mixed infection, non-falciparum species only |
|                                           | Designated type: Type 2 | Batch numbers: 100088 for the first 393 tests, and 041388 for the remaining 167 tests                                                   |
|                                           | Transport and storage conditions: Not described | Person(s) performing RDT: Performed by trained health workers and read by a study physician blinded to the microscopy results |
|                                           | RDT setting: Primary health centre                        |                                                                                                                                            |
| Follow-up                                 | Not applicable                                                                                             |                                                                                                                                            |
| Notes                                     | Source of funding: Financial assistance received from the Northern Territory Government 50th Anniversary of Indonesian Independence Malaria-Tuberculosis Research Fellowships. ICT Pf/Pv kits and some logistical costs were supported by AMRAD-ICT Sydney, New South Wales, Australia |

Table of Methodological Quality

| Item                                      | Authors’ judgement | Description                                                                                                                                 |
|-------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                  | Unclear            | Participants were all attending a primary health care centre with fever and symptoms of malaria, but the sampling method was not described       |
| All tests                                 |                    |                                                                                                                                            |
| Acceptable reference standard?            | Yes                | All slides were read by an experienced microscopist viewing at least 100 high power fields, and results discordant with RDT were re-examined by another, independent microscopist |
| All tests                                 |                    |                                                                                                                                            |
| Partial verification avoided?             | Yes                | All participants who received the index test also received the reference test                                                               |
| All tests                                 |                    |                                                                                                                                            |
| Differential verification avoided?        | Yes                | The same reference test was used regardless of the index test results                                                                       |
| All tests                                 |                    |                                                                                                                                            |
| Incorporation avoided?                   | Yes                | The index test does not form part of the reference standard.                                                                                |
| All tests                                 |                    |                                                                                                                                            |
| Reference standard results blinded?       | Yes                | “The microscopist was unaware of the immunochromatographic test result”                                                                       |
| All tests                                 |                    |                                                                                                                                            |
| Index test results blinded?               | Yes                | “The results were read by a study physician who was blinded to the microscopy results”                                                       |
| All tests                                 |                    |                                                                                                                                            |
**Tjitra 1999** *(Continued)*

| Parameters                          | Details                                                                 |
|------------------------------------|-------------------------------------------------------------------------|
| Uninterpretable results reported?  | Unclear                                                                 |
| All tests                          | The number of participants enrolled in the study was clearly stated and correspond to the number presented in the analysis; therefore there were no exclusions due to uninterpretable test results |
| Withdrawals explained?             | Yes                                                                     |
| All tests                          | The number of participants enrolled in the study was clearly stated and corresponded to the number included in the analysis; therefore there were no withdrawals |

**Trouvay 2013**

**Clinical features and settings**

- **Presenting signs and symptoms:** Febrile patients who consulted for suspected malaria
- **Previous treatment for malaria:** Not reported on, but there were no exclusion criteria based on antimalarial use
- **Clinical setting:** Not clear
- **Country:** French Guiana
- **Malaria endemicity:** At a low number of focal points on the coast, associated with gold mining
- **Malaria endemic species:** 31% *P. falciparum* and 68.5% *P. vivax*. *P. malariae* cases are occasional.

**Participants**

- **Sample size:** 960
- **Age:** All ages eligible. Actual age range of the participants 1 to 92 years (median age 25.8 years)
- **Sex:** Males and females eligible; ratio of male to female was 1.2:1
- **Co-morbidities:** Not mentioned either as an exclusion criteria or a characteristic of the included participants
- **Parasite density of microscopy positive cases:** *P. vivax* mean 0.11%

**Study design**

Enrolment was prospective, with all eligible participants were included. 1 RDT was tested

**Target condition and reference standard(s)**

- **Target condition:** Malaria parasitaemia
- **Reference standard:** Microscopy thick and thin blood smears
- **Who performed the reference standard tests, and where?** An expert microscopist at Cayenne Hospital laboratory
- **If microscopy was used, how many high power fields were looked at?** 200 fields in the thin film
- **How many observers or repeats were used?** 1 observer.
- **How were discrepancies between observers resolved?** Not applicable. However, PCR was conducted on samples where microscopy and RDT gave different results

**Index and comparator tests**

- **Commercial name of RDT:** SD malaria Ag Pf/Pan
- **Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum species only
- **Designated type:** Type 3
Trouvay 2013 (Continued)

| Item                          | Authors’ judgement | Description                                                                                                                                 |
|-------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?      | Yes                | All febrile patients who consulted with suspected malaria during a prospective study were initially included. *P. malariae* cases were subsequently excluded, however, only 3 of 960 enrolled participants were excluded for this reason |
| Acceptable reference standard?| No                 | Only 1 microscopist was used. In case of discordant results between RDT and microscopy, PCR was used to determine infections and species. However, the PCR results were not used to adjust the microscopy results |
| Partial verification avoided? | Yes                | All participants who received the index test also received the reference test                                                                 |
| Differential verification avoided? | Yes            | The same reference test was used regardless of the index test results                                                                       |
| Incorporation avoided?        | Yes                | The index test does not form part of the reference standard.                                                                                   |
| Reference standard results blinded? | Yes              | The microscopic examination was carried out simultaneously.                                                                                     |
| Index test results blinded?   | Yes                | Interpretation of the test was carried out independently of the microscopic examination                                                      |
| Uninterpretable results reported? | Yes              | No invalid RDTs were observed.                                                                                                                  |
| Withdrawals explained?        | Yes                | There were 3 exclusions post-enrolment, due to *P. malariae* infection.                                                                     |
### Clinical features and settings

**Presenting signs and symptoms:** Fever or history of fever  
**Previous treatment for malaria:** Not mentioned, either as an exclusion criteria or a characteristic of included participants  
**Clinical setting:** Malaria clinics and village health workers  
**Country:** India (Delhi, Nadiad, Jabalpur and Sonapur)  
**Malaria endemicity:** 4 sites of different endemicities  
**Malaria endemic species:** *P. falciparum* and *P. vivax*

### Participants

**Sample size:** 699  
**Age:** All ages eligible; age range of included participants 1 to 75 years (mean 22.8)  
**Sex:** Included 395 males and 304 females  
**Co-morbidities:** Not mentioned, either as an exclusion criteria or a characteristic of included participants  
**Parasite density of microscopy positive cases:**  
- *P. vivax* range 40 to 44,000 parasites/µL, median 1020  
- *P. falciparum* range 120 to 68,480 parasites/µL, median 2000

### Study design

**Enrolment was prospective. The sampling method was not described. 1 RDT was tested**

### Target condition and reference standard(s)

**Target condition:** Malaria parasitaemia  
**Reference standard:** Microscopy  
**Who performed the reference standard tests, and where?** Microscopist. Setting was not stated  
**If microscopy was used, how many high power fields were looked at?** 100  
**How many observers or repeats were used?** 1 for most slides. All results discordant with RDT results and 20% of concordant results were cross-checked. Negative slides which tested positive by kit were re-examined by counting up to 2000 WBCs  
**How were discrepancies between observers resolved?** In the case of initially negative slides looked at in more detail because of discordant results, the second reading was taken as true

### Index and comparator tests

**Commercial name of RDT:** OptiMAL (DiaMed, AG, Cressier, Switzerland)  
**Parasite(s) designed to detect:** *P. falciparum* or mixed infection, non-falciparum species only  
**Designated type:** Type 4  
**Batch numbers:** 46050.24.05  
**Transport and storage conditions:** Stored below 30°C  
**Person(s) performing RDT:** Not stated  
**RDT setting:** At the study sites (clinic and villages)

### Follow-up

**Not applicable**

### Notes

**Source of funding:** Not stated

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**Table of Methodological Quality**

| Item | Authors’ judgement | Description |
|------|---------------------|-------------|

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*Copyright © 2014 The Authors. The Cochrane Database of Systematic Reviews published by John Wiley & Sons, Ltd. on behalf of The Cochrane Collaboration.*
| **Representative spectrum?** | Unclear | All participants were all attending clinics or approaching village health workers with fever or history of fever, but the sampling method was not described. |
|-------------------------------|---------|----------------------------------------------------------------------------------------------------------------------------------|
| **Acceptable reference standard?** | Unclear | Microscopists viewed 100 high power fields before declaring a slide negative, and results discordant with RDTs were cross-checked. However, it is not clear whether the person doing the cross-checking was a different microscopist working independently. |
| **Partial verification avoided?** | Yes | All participants who received the index test also received the reference test. |
| **Differential verification avoided?** | Yes | The same reference test was used regardless of the index test results. |
| **Incorporation avoided?** | Yes | The index test does not form part of the reference standard. |
| **Reference standard results blinded?** | Yes | “Microscopists were blinded to the rapid test results”. |
| **Index test results blinded?** | Yes | The RDT was done before the microscopy. |
| **Uninterpretable results reported?** | No | The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any exclusions due to uninterpretable test results. |
| **Withdrawals explained?** | Unclear | The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any withdrawals. |
### Clinical features and settings

**Presenting signs and symptoms:** New episode of suspected malaria, which could include fever, history or other complaints indicating possible malaria infection

**Previous treatment for malaria:** Excluded if malaria confirmed (treated or untreated) within the previous 4 weeks

**Clinical setting:** Malaria outpatient centre

**Country:** Colombia

**Malaria endemicity:** Hypoendemic, annual parasite rate 2 to 5%

**Malaria endemic species:** 
- *P. vivax* (54%)
- *P. falciparum* (46%)

### Participants

**Sample size:** 896

**Age:** All ages eligible. Actual numbers of children and adults not stated, although the report mentions that many workers were included.

**Sex:** Both males and females eligible. Most of the participants were male (646, 79%)

**Co-morbidities and pregnancy:** No exclusions criteria based on co-morbidities. No details of the frequency of these conditions in the participant population is presented

**Parasite density of microscopy positive cases:** Geometric mean approximately 2300 parasites per µL for both *P. falciparum* and *P. vivax*

### Study design

Enrolment was prospective. The sampling method was not described. 3 RDTs were tested. All individuals received all 3 tests

### Target condition and reference standard(s)

**Target condition:** Malaria parasitaemia

**Reference standard:** Microscopy thick and thin blood smears

**Person(s) performing microscopy:** Well trained, experienced microscopists

**Microscopy setting:** Not stated

**Number of high power fields examined before declaring negative:** At least 200

**Number of observer or repeats:** 1, except for about one third of the slides (especially low density parasitaemias and mixed infections). In this case, another microscopist viewed the slide and discordant results between microscopists or between slides and RDTs were sent to the University of Antioquia for external cross-checking

**Resolution of discrepancies between observers:** Disagreements between the internal and external results were sent to a third laboratory, of the National Health Institute in Bogota. In cases where both external laboratories disagreed with the internal laboratory, results were corrected accordingly

### Index and comparator tests

**Commercial name of RDT:**
- Paracheck Pf (Orchid Biomedical Systems, Goa, India)
- OptiMAL-IT (Diamed AG, Switzerland)
- NOW Malaria ICT (Binax, Portland, USA)

**Parasite(s) designed to detect:**
- Paracheck Pf - *P. falciparum*
- OptiMAL-IT - *P. falciparum* or mixed infection, non-falciparum species only
- NOW Malaria ICT - *P. falciparum* or mixed infection, non-falciparum species only

**Designated type:**
- Paracheck Pf - Type 1
- Parascreen - Type 3
- OptiMAL - Type 4

**Batch numbers:** Not stated
van den Broek 2006  (Continued)

| Item                              | Authors' judgement | Description                                                                                                                                 |
|-----------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Transport and storage conditions:| Not described      |                                                                                                                                             |
| Person(s) performing RDT:         | A bacteriologist.  | Where the result was ambiguous, 2 bacteriologists read the test results                                                                   |
| RDT setting:                      | At the malaria centre |                                                                                                                                           |
| Follow-up                         | Not applicable     |                                                                                                                                             |
| Notes                             | Source of funding: Medicins Sans Frontières, Holland, and its donors. The American Society of Tropical Medicine and Hygiene assisted with publication expenses |

Table of Methodological Quality

| Item                              | Authors' judgement | Description                                                                                                                                 |
|-----------------------------------|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?          | Unclear            | All participants were patients presenting with suspected malaria, but the sampling method was not described                                 |
| Acceptable reference standard?    | No                 | Microscopists viewed at least 200 high power fields before declaring a slide negative; however the findings were only verified by a second independent reader for a third of slides |
| Partial verification avoided?     | Yes                | All participants who received the index test also received the reference test                                                               |
| Differential verification avoided?| Yes                | The same reference test was used regardless of the index test results                                                                       |
| Incorporation avoided?            | Yes                | The index test does not form part of the reference standard,                                                                                   |
| Reference standard results blinded?| Yes                | Report states that microscopists were blinded to the results of RDTs                                                                        |
| Index test results blinded?       | Yes                | Report states that RDTs were blinded to the results of microscopy                                                                             |
| Uninterpretable results reported? | Yes                | There were no uninterpretable results; and weak lines were scored as positive                                                               |
|Withdrawals explained?             | Unclear            | The number of participants originally enrolled in the study was not explicitly stated; therefore it was not possible to assess whether there were any withdrawals |
Clinical features and settings

- **Presenting signs and symptoms**: Oral temperature over 38°C, headache or a history of fever in the previous 72 hours
- **Previous treatment for malaria**: No exclusions based on previous episodes or treatment for malaria; no data presented on recent antimalarial use in the children
- **Clinical setting**: Malaria clinics
- **Country**: Thailand (Maesod)
- **Malaria endemicity**: Not stated
- **Malaria endemic species**: *P*. *falciparum* and *P*. *vivax*.

Participants

- **Sample size**: 246
- **Age**: Inclusion criteria stipulated over 20 years old
- **Sex**: Both males and females were eligible
- **Co-morbidities and pregnancy**: Not mentioned, either as an exclusion criteria or characteristic of the included participants
- **Parasite density of microscopy positive cases**: Not presented

Study design

- **Enrolment**: Prospective. The sampling method was not described. 1 RDT was tested

Target condition and reference standard(s)

- **Target condition**: Malaria parasitaemia
- **Reference standard**: Microscopy thick and thin blood smears
- **Who performed the reference standard tests, and where?**: Experienced microscopists at the Armed Forces Research Institute of Medical Sciences
- **If microscopy was used, how many high power fields were looked at?**: 200
- **How many observers or repeats were used?**: 2 independent observers, blinded to each others findings
- **How were discrepancies between observers resolved?**: Resolved by a third expert microscopist, whose reading was accepted as final. Where there was species discrepancy between microscopy and NOW ICT, PCR was done

Index and comparator tests

- **Commercial name of RDT**: NOW ICT Malaria Pf/Pv
- **Parasite(s) designed to detect**: *P*. *falciparum* or mixed infection, non-falciparum species only
- **Designated type**: Type 2
- **Batch numbers**: 030611
- **Transport and storage conditions**: Not described
- **Person(s) performing RDT**: Technician
- **RDT setting**: Armed Forces Research Institute of Medical Sciences

Follow-up

- **Not applicable**

Notes

- **Source of funding**: US Army Medical Material Development Activity

Table of Methodological Quality

| Item | Authors' judgement | Description |
|------|--------------------|-------------|
### Wongsrichanalai 2003 (Continued)

| Question                                      | All tests | Description                                                                                                                                 |
|-----------------------------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------|
| Representative spectrum?                      | Unclear   | All participants were attending malaria clinics with temperature over 38°C, headache or a history of fever in the previous 72 hours, but the sampling method was not adequately described |
| Acceptable reference standard?                | Yes       | 2 independent microscopists at a research laboratory viewed at least 200 high power fields before declaring a slide negative                  |
| Partial verification avoided?                 | Yes       | All participants who received the index test also received the reference test                                                             |
| Differential verification avoided?            | Yes       | The same reference test was used regardless of the index test results                                                                       |
| Incorporation avoided?                        | Yes       | The index test does not form part of the reference standard.                                                                                  |
| Reference standard results blinded?           | Yes       | “read by two microscopists blinded to...the NOW ICT results”                                                                                   |
| Index test results blinded?                   | Yes       | The RDT was carried out before microscopy.                                                                                                |
| Uninterpretable results reported?             | Yes       | The RDTs had to be repeated in 39 of 285 assays. A successful test was eventually completed for each sample                               |
| Withdrawals explained?                        | Yes       | The number of participants enrolled in the study was clearly stated and corresponded with the number included in the analysis, indicating no withdrawals |

### Xiaodong 2013

#### Clinical features and settings
- **Presenting signs and symptoms:** Suspected malaria
- **Previous treatments for malaria:** Not reported.
- **Clinical setting:** TengChong CDC, China and Health Unlimited clinic in Myanmar (China-Myanmar border)
- **Country:** China, Myanmar
- **Malaria endemicity:** Endemic
- **Malaria endemic species:** *P. falciparum, P. vivax*

#### Participants
- **Sample size:** 241
- **Age:** Mean 29.62 (11.21), range 3 to 58 years
- **Sex:** 78.01% male, 21.99% female
- **Co-morbidities or pregnancy:** Not reported
| Study design | Participants prospectively enrolled, not reported whether participants consecutively enrolled. The study evaluated 1 RDT |
|-------------|---------------------------------------------------------------------------------------------------------------|
| Target condition and reference standard(s) | **Type(s) of malaria parasite tested for:** *P. falciparum* and *P. vivax*  
**Reference standard test(s) used:** Microscopy (thick and thin blood smears) corrected by PCR assays  
**Who performed the reference standard tests, and where?** The microscopic evaluation was done by experienced microscopists. Place not reported. Not reported for PCR.  
**If microscopy was used, how many high power fields were looked at?** 100 fields  
**How many observers or repeats were used?** 2 independent microscopists. Also, a double-blind cross reading of a random 50 blood slides was performed by a senior microscopist.  
**How were discrepancies between observers resolved?** In the case of discordant results between microscopy and PCR, the results of PCR were used as the standard method |
| Index and comparator tests | **Commercial name of the test:** CareStart malaria HRP2/pLDH (Pf/pan) combo test  
**Parasite species the test is designed to detect:** Multi species  
**Designated type:** Type 3  
**Batch numbers:** C201R  
**Transport and storage conditions:** Not reported.  
**Who performed the index test, and where?** 3 health worker-observers. Place not reported. |
| Follow-up | Not applicable |
| Notes | **Source of funding:** Source of funding not reported. CDC (Chinese Center for Disease Control and Prevention). It is stated that individual biodata and malaria history in the previous 1 year were documented from each suspected case. However, co-morbidities and treatment history have not been reported. Index test was performed by 3 health worker-observers: the first observer performed readings at 20 minutes (recommended by the manufacturer) and the other 2 observers, within the next 10 minutes |

### Table of Methodological Quality

| Item | Authors’ judgement | Description |
|------|-------------------|-------------|
| Representative spectrum?  
All tests | Yes | Consecutive patients with suspected malaria were enrolled. Then all patients who were positive for malaria by microscopy and a random sample of negative samples were included in the analysis |
| Acceptable reference standard?  
All tests | Yes | Microscopy was undertaken by 2 independent experienced microscopists (100 fields) and species identifications was conformed PCR assays |
### Partial verification avoided?
*All tests* | Yes | All participants receiving the index tests had their diagnosis verified by reference standard.

### Differential verification avoided?
*All tests* | Yes | Microscopy was used as a reference standard for all samples, regardless of index test.

### Incorporation avoided?
*All tests* | Yes | Microscopy and PCR was used.

### Reference standard results blinded?
*All tests* | Unclear | Blinding of microscopists not reported.

### Index test results blinded?
*All tests* | Yes | The 3 observers were blinded to each other’s readings and to the results of microscopy and PCR assay.

### Uninterpretable results reported?
*All tests* | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results. In case the index test result was considered invalid, the test was repeated.

### Withdrawals explained?
*All tests* | Yes | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals.

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### Yan 2013

#### Clinical features and settings

- **Presenting signs and symptoms:** Suspected uncomplicated malaria, fever with axillary temperature above 37.5°C at the time of examination.
- **Previous treatments for malaria:** Not reported.
- **Clinical setting:** Local malaria clinics and hospitals at the Laiza township.
- **Country:** Myanmar (China-Myanmar border).
- **Malaria endemicity:** Endemic. Seasonal; mostly in the rainy season from April to November.
- **Malaria endemic species:** Predominantly *P. falciparum* and *P. vivax*.

#### Participants

- **Sample size:** 606.
- **Age:** Median 20.3 years, range 6 months to 88 years.
- **Sex:** ~50% male, 50% female.
- **Co-morbidities or pregnancy:** Not reported.
Yan 2013  (Continued)

| Study design | Participants prospectively enrolled, not reported whether participants consecutively enrolled. All 606 samples were evaluated microscopically and by One Step Malaria Pf/Pan test. A subset of 350 were also evaluated by Malaria Pv/Pf test device |
| --- | --- |

| Target condition and reference standard(s) | **Type(s) of malaria parasite tested for**: Multiple species; falciparum and non-falciparum.  
**Reference standard test(s) used**: Microscopy thick and thin blood smears and PCR  
**Who performed the reference standard tests, and where?** The reference standard was performed by experienced microscopists. Location not reported. Not reported for PCR  
**If microscopy was used, how many high power fields were looked at?** 100 fields  
**How many observers or repeats were used?** 2 independent microscopists  
**How were discrepancies between observers resolved?** The results were combined |
| --- | --- |

| Index and comparator tests | **Commercial name of the test:**  
• One Step Malaria Pf/Pan test (Wondfo, China)  
• Malaria Pv/Pf test device (Tycolpharm Co., Limited, UK)  
**Parasite species the test is designed to detect:**  
• One Step Malaria Pf/Pan test: *P. falciparum* and all human *Plasmodium* species  
• Malaria Pv/Pf test device: *P. falciparum* and *P. vivax*  
**Designated type:**  
• One Step Malaria Pf/Pan test: Type 3  
• Malaria Pv/Pf test device: HRP-2 antigen for *P. falciparum* and pLDH antigen for *P. vivax*  
**Batch numbers:** Not reported  
**Transport and storage conditions:** Not reported  
**Who performed the index test and where?** Not reported |
| --- | --- |

| Follow-up | Not applicable |
| --- | --- |

| Notes | **Source of funding:** The National Institute of Allergy and Infectious Diseases, National Institutes of Health (U19 AI089672) |
| --- | --- |

| Table of Methodological Quality |
| --- | --- | --- |
| **Item** | **Authors’ judgement** | **Description** |
| --- | --- | --- |
| Representative spectrum?  
All tests | Unclear | Patients with suspected malaria, having fever with axillary temperature above 37.5°C were included in the study. Sampling method was not reported, only a subsample received Pf/Pv test and sampling method for this not described |
| Acceptable reference standard?  
All tests | Yes | Microscopy was performed by 2 independent microscopists. 100 fields. PCR was also done |
| Partial verification avoided?  
All tests | Yes | All participants receiving the index tests had their diagnosis verified by the reference standard |

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Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)  
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Yan 2013  (Continued)

|                                |  | test                                                                 |
|--------------------------------|---|----------------------------------------------------------------------|
| Differential verification avoided? | | The same reference test was used.                                    |
| All tests                      | Yes|                                                                      |
| Incorporation avoided?         | | The reference test was microscopy and PCR.                          |
| All tests                      | Yes|                                                                      |
| Reference standard results blinded? | | The microscopists were blinded to the results of additional diagnostic tests |
| All tests                      | Yes|                                                                      |
| Index test results blinded?    | | The readers of RDTs were blinded to the results of microscopy and PCR |
| All tests                      | Yes|                                                                      |
| Uninterpretable results reported? | Unclear | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals due to invalid results |
| All tests                      | Unclear|                                                                |
| Withdrawals explained?         | | Number enrolled in the study was explicitly stated and corresponded to the number presented in the analysis; therefore there were no withdrawals |
| All tests                      | Yes|                                                                      |

**Characteristics of excluded studies  [ordered by study ID]**

| Study             | Reason for exclusion                                    |
|-------------------|---------------------------------------------------------|
| A-Elgayoum 2009   | Not a study of RDTs (compared usual with expert microscopy). |
| Abeku 2008        | No data presented on non-falciparum malaria.            |
| Abul Faiz 2000    | Participants had cerebral malaria.                       |
| Ademowo 2012      | *P. falciparum* malaria only.                           |
| Adesanmi 2011     | *P. falciparum* malaria only.                           |
| Afzaal 2001       | Review or narrative.                                    |
| Ahmad 2003        | Report does not contain enough information to assess eligibility |
| Ahmed 2010        | Case-control study.                                    |
| Albertini 2012    | Not a DTA study.                                        |
| Reference                  | Description                                                                 |
|----------------------------|-----------------------------------------------------------------------------|
| Allen 2011                 | *P. falciparum* malaria only.                                               |
| Anonymous 2005             | Review or narrative.                                                        |
| Ansah 2008                 | Report does not contain enough information to assess eligibility             |
| Ansah 2010                 | *P. falciparum* malaria only.                                               |
| Araz 2000                  | Some participants did not have symptoms of malaria.                         |
| Arkanjo 2007               | Non-English language.                                                       |
| Ardic 2012                 | Non-English language.                                                       |
| Arora 2003                 | Participants have severe or complicated malaria.                            |
| Arróspide 2004a            | Most participants had no symptoms of malaria.                               |
| Arróspide 2004b            | Non-English language.                                                       |
| Arróspide 2006             |                                                                                |
| Ashley 2009                | Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Aslan 2001                 | Participants were hospital inpatients.                                      |
| Assal 1999                 | Not immunochromatographic RDTs.                                             |
| Avila 2002                 | Participants were travellers returning from an endemic to a non-endemic region |
| Ayeh-Kumi 2011             | *P. falciparum* malaria only.                                               |
| Azazy 2004                 | Only participants with malaria positive blood films by microscopy received the RDT |
| Azikiwe 2012               | *P. falciparum* malaria only.                                               |
| Babacar 2008               | Not a DTA study.                                                            |
| Baiden 2012                | *P. falciparum* malaria only.                                               |
| Balrzell 2013              | Not a DTA study.                                                            |
| Banchongaksorn 1996        | No data presented on non-falciparum malaria.                                |
| Banchongaksorn 1997        | No data presented on non-falciparum malaria.                                |
Barber 2013 | Only participants with malaria positive blood films by microscopy were included
---|---
Bartoloni 1998 | Single case study.
Bassene 2009 | Not a DTA study.
Bassett 1991 | Not a DTA study.
Batwala 2011 | *P. falciparum* malaria only.
Beadle 1994 | Most participants did not have symptoms of malaria.
Bechem 1999 | Did not present sufficient data to enable extraction of the numbers of true positives, false positive, true negatives and false positives
Beg 2005 | All participants were positive for malaria by microscopy.
Belizario 2005 | Participants were recruited by active case finding.
Bell 2005 | Not a consecutive sample: excluded a random sample of participants who were negative for malaria by microscopy
Bell 2006 | Review or narrative.
Bellagra 1998 | Participants were travellers returning from an endemic to a non-endemic area
Bendezu 2008 | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives
Berens-Riha 2009 | Subjects were dead.
Bhandari 2008 | All participants were positive for malaria by microscopy.
Bhat 2012 | Recruited from a tertiary care hospital.
Bhatt 1994 | Review or narrative.
Birku 1999 | Participants had severe or complicated malaria.
Bisoffi 2009a | Not a DTA study.
Bisoffi 2009b | Review or narrative.
Bisoffi 2011 | Not a DTA study.
Biswas 2004 | Not a DTA study.
| Authors            | Notes                                                                 |
|--------------------|----------------------------------------------------------------------|
| Biswas 2006        | Not an immunochromatographic test.                                   |
| Bjorkman 2011      | Report does not contain enough information to assess eligibility     |
| Bojang 1999        | No data presented on non-falciparum malaria.                        |
| Bouchaud 2000      | Participants were travellers returning from endemic to non-endemic areas |
| Bouyou Akotet 2013 | Unable to extract raw data.                                         |
| Brenier-Pinchart 2000 | Participants were travellers returning from endemic to non-endemic areas |
| Bruxvoort 2008     | Participants were recruited by active case finding.                 |
| Bualombai 2003     | No data presented on non-falciparum malaria.                        |
| Bualombai 2008     | Report does not contain enough information to assess eligibility     |
| Buchachart 2004    | Participants are hospital in-patients.                               |
| Buhalata 2011      | *P. falciparum* malaria only.                                        |
| Bujanover 2002     | Not a DTA study.                                                    |
| Cabezas 2004       | Not a DTA study (comparing 'field' and laboratory RDT results)       |
| Caraballo 1996     | No data presented on non-falciparum malaria.                        |
| Carmona Fonseca 2010 | Non-English language.                                            |
| Cavallo 1997       | Participants were travellers returning from endemic to non-endemic countries |
| Chaijaroenkul 2011 | Included participants without symptoms of malaria.                  |
| Chatterjee 2008    | Report did not contain enough information to assess eligibility      |
| Cheng 2006         | Review or narrative.                                                |
| Chilton 2006       | Not a DTA study.                                                    |
| Chinkhumba 2010    | *P. falciparum* malaria only.                                        |
| Chinkhumba 2012    | *P. falciparum* malaria only.                                        |
| Chiodini 1998      | Review or narrative.                                                |
| Study   | Note                                                                                                                                 |
|---------|-------------------------------------------------------------------------------------------------------------------------------------|
| Chiodini 2005 | Not a DTA study.                                                                                                                 |
| Chitkara 2004 | No data presented on non-falciparum malaria.                                                                                     |
| Cho 2001    | Not undertaken in a malaria endemic area.                                                                                         |
| Cho 2011    | Case-control study in travellers returning from an endemic to a non-endemic area                                                  |
| Cnops 2011  | Samples not collected in a malaria endemic area.                                                                                   |
| Coleman 2002a | Most participants did not have symptoms of malaria.                                                                                |
| Coleman 2002b | Most participants did not have symptoms of malaria.                                                                                |
| Cong le 2002 | Non-English language.                                                                                                             |
| Cooke 1999  | No data presented on non-falciparum malaria.                                                                                      |
| Craig 1997  | Tested blood films with artificially cultured and diluted malaria parasites                                                     |
| Craig 2002  | The participants were positive for malaria by microscopy.                                                                         |
| Cropley 2000 | Participants were travellers returning from endemic to non-endemic areas                                                         |
| Cuadros 2007 | Participants were travellers returning from endemic to non-endemic areas                                                         |
| Davoodian 2011 | Not enough information presented to judge eligibility.                                                                           |
| Dawoud 2008 | No data presented on non-falciparum malaria.                                                                                      |
| de Carsalade 2009 | Non-English language.                                                            |
| de Dominguez 1996 | Not a DTA study.                                                                                                   |
| De Monbrison 2004 | Participants were travellers returning from endemic to non-endemic areas                                                           |
| de Oliveira 2007 | No data presented on non-falciparum malaria.                                                                                     |
| Delaunay 2008 | Review or narrative.                                                                                                             |
| Deleoitille 1987 | Not commercially available RDTs.                                                                                                 |
| Devi 2002    | No data presented on non-falciparum malaria.                                                                                      |
| Di Perry 1997 | All participants were positive for malaria by microscopy.                                                                         |
| Di Santi 2011 | Positive and negative blood samples selected for the study.                                                                       |
| Reference | Description |
|-----------|-------------|
| Diarra 2012 | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives for individual malaria species. |
| Dietze 1995 | Some participants did not have symptoms of malaria. |
| Drakeley 2009 | Review or narrative. |
| Dubarry 1990 | Not evaluating an immunochromatographic RDT. |
| Durand 2005 | Review or narrative. |
| Durand 2007 | Participants were travellers returning from endemic to non-endemic areas. |
| Durrheim 1998 | No data presented on non-falciparum malaria. |
| Dyer 2000 | All participants were positive for malaria by microscopy. |
| Dzakah 2013 | Positive and negative blood samples selected for the study. |
| Eisen 2000 | Not undertaken in a malaria endemic area. |
| El-Moamly 2007 | Participants were travellers returning from a malaria endemic to a non endemic area. |
| Elmardi 2009 | Not a DTA study. |
| Endeshaw 2008 | Most participants did not have symptoms of malaria. |
| Endeshaw 2010 | Unable to extract raw data for 2 x 2 table. |
| Existe 2010 | Not enough information presented to judge eligibility. |
| Falade 2013 | *P. falciparum* malaria only. |
| Fan 2000 | Non-English language. |
| Fancony 2013 | Included asymptomatic individuals (population survey). |
| Farcas 2003 | Participants were travellers returning from endemic to non-endemic areas. |
| Farcas 2004 | Not an immunochromatographic test. |
| Ferro 2002 | Participants were travellers returning from an endemic area to an non-endemic area. |
| Figueiredo Filho 2003 | All participants were positive for malaria by microscopy. |
| Fogg 2008 | No data presented on non-falciparum malaria. |
| Reference       | Description                                                                 |
|-----------------|-----------------------------------------------------------------------------|
| Forney 2001     | No data presented on non-falciparum malaria.                                |
| Forney 2003     | No data presented on non-falciparum malaria.                                |
| Fryauff 1997    | Report did not contain enough information to assess eligibility.            |
| Fryauff 2000    | Participants did not have symptoms of malaria.                             |
| Funk 1999       | Participants were travellers returning from endemic to non-endemic areas.   |
| Garavelli 2002  | Participants were travellers returning from endemic to non-endemic areas.   |
| Garcia 1996     | Report did not contain enough information to assess eligibility.            |
| Gatti 2002      | Participants were travellers returning from endemic to non-endemic areas.   |
| Gatti 2007      | Participants were travellers returning from endemic to non-endemic areas.   |
| Gaye 1998       | No data presented on non-falciparum malaria.                                |
| Gaye 1999       | No data presented on non-falciparum malaria.                                |
| Gelaglie 2010   | Not enough information presented to judge eligibility.                     |
| Gerstl 2009     | No data presented on non-falciparum malaria.                                |
| Ghanchi 2009    | Not a DTA study.                                                           |
| Ghosh 2000      | No data presented on non-falciparum malaria.                                |
| Ghouth 2012     | *P. falciparum* malaria only.                                               |
| Gillet 2009a    | Participants were travellers returning from endemic to non-endemic areas.   |
| Gillet 2009b    | Not a DTA study.                                                           |
| Gillet 2009c    | Participants were travellers returning from an endemic to a non-endemic area|
| Gillet 2011     | Not a DTA study; patients negative by reference standard standard were excluded|
| Gogtay 1999     | Participants had severe or complicated malaria.                            |
| Gogtay 2003     | Participants were all positive for malaria by blood smear.                  |
| Goh 2013        | Does not evaluate an RDT.                                                  |
| Reference | Notes |
|-----------|-------|
| Gomes 2013 | Selected positive and negative samples by reference test. |
| Gonzáles-Cerón 2005 | Non-English language. |
| Grobusch 1999 | Not undertaken in a malaria endemic area. |
| Grobusch 2002 | Not undertaken in a malaria endemic area. |
| Grobusch 2003a | Participants were travellers returning from endemic to non-endemic areas |
| Grobusch 2003b | Participants were travellers returning from endemic to non-endemic areas |
| Gupta 2001 | Some participants had severe or complicated malaria. |
| Guthmann 2002 | No data presented on non-falciparum malaria. |
| Gutierrez 2005 | Not a DTA study. |
| Hada 2011 | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives for individual malaria species |
| Haditsch 2004 | Review or narrative. |
| Hance 2005 | Review or narrative. |
| Happi 2004 | All participants were positive for malaria by microscopy. |
| Harchut 2013 | *P. falciparum* malaria only. |
| Hashizume 2006 | Participants were displaced people from mainly very low endemicity areas |
| Hawkes 2009 | Not a DTA study. |
| Hernandes 2001 | Participants were travellers returning from endemic to non-endemic areas |
| Holmberg 1992 | Not a DTA study. |
| Hopkins 2007 | No data presented on non-falciparum malaria. |
| Hopkins 2008 | No data presented on non-falciparum malaria. |
| Hossain 2008 | Participants had severe or complicated malaria. |
| Houmsou 2011 | Report does not contain enough information to assess eligibility |
| Houzé 2009 | All participants were positive for malaria by microscopy. |
| Reference         | Notes                                                                 |
|-------------------|----------------------------------------------------------------------|
| Houzé 2011        | Participants were travellers returning from endemic to non-endemic areas |
| Humar 1997        | Participants were travellers returning from endemic to non-endemic areas |
| Huong 2002        | Not based on a consecutive sample; included a group malaria positive by microscopy and an asymptomatic malaria negative control group |
| Hänscheid 1999   | Review or narrative.                                                  |
| Iqbal 2000        | Not a consecutive sample: participants were selected to have a high risk of rheumatoid factor |
| Iqbal 2001        | Participants were travellers returning from endemic to non-endemic areas |
| Iqbal 2002        | Participants were travellers returning from endemic to non-endemic areas |
| Iqbal 2003        | No data presented on non-falciparum malaria.                         |
| Iqbal 2004        | All participants were positive for malaria by microscopy.             |
| Ishengoma 2011    | *P. falciparum* malaria only.                                         |
| Jang 2013         | Participants were travellers returning from endemic to non-endemic areas |
| Jelinek 1996      | Does not evaluate an immunochromatographic RDT for malaria.           |
| Jelinek 1999      | Participants were travellers returning from endemic to non-endemic areas |
| Jelinek 2000      | Participants were travellers returning from endemic to non-endemic areas |
| Jelinek 2001      | Participants were travellers returning from endemic to non-endemic areas |
| Jeurissen 1999    | Review or narrative.                                                  |
| John 1998         | All participants were positive for malaria by microscopy.             |
| Joshi 2004        | Not evaluating an immunochromatographic RDT.                         |
| Kaewsonthi 1996   | Not a DTA study.                                                      |
| Kahama-Maro 2008  | Report does not contain enough information to assess eligibility      |
| Kahama-Maro 2011  | No data presented on non-falciparum malaria.                         |
| Kakkilaya 2003    | Review or narrative.                                                  |
| Kamugisha 2008    | Most participants did not have symptoms of malaria.                   |
| Reference       | Description                                                                 |
|-----------------|-----------------------------------------------------------------------------|
| Kar 1998        | No data presented on non-falciparum malaria.                               |
| Karbwang 1996  | All participants were positive for malaria by microscopy.                   |
| Karimov 2011    | Non-English language.                                                       |
| Kashif 2013     | *P. falciparum* malaria only.                                               |
| Katakai 2011    | Positive and negative blood samples selected for the study.                |
| Kattenberg 2011 | Not enough information presented to judge eligibility.                     |
| Kaur 2000       | All participants had cerebral malaria.                                      |
| Kaushal 1995    | Tested for *P. knowlesi* infection in monkeys.                             |
| Kaushal 1997    | Review or narrative.                                                        |
| Kawai 2009      | Tested for *P. knowlesi* infection in monkeys.                             |
| Keating 2009    | Most participants did not have symptoms of malaria.                         |
| Khairnar 2009   | Participants were travellers returning from an endemic to a non-endemic area|
| Khan 2004       | Participants were hospital inpatients.                                     |
| Kilian 1997     | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Kilian 1999     | No data presented on non-falciparum malaria.                               |
| Kim 2008        | Includes a symptomatic group with malaria infection identified by microscopy, and an asymptomatic group with no malaria infection by microscopy |
| Kim 2011        | Only participants with malaria positive blood films by microscopy received the RDT |
| Kim 2013        | Includes a symptomatic group with malaria infection identified by microscopy, and an asymptomatic group with no malaria infection by microscopy |
| Knappik 2002    | Participants were travellers returning from endemic to non-endemic areas    |
| Kodisinghe 1997 | Some participants did not have symptoms of malaria.                         |
| Koita 2012      | *P. falciparum* malaria only.                                               |
| Kumar 1996      | No data presented on non-falciparum malaria.                               |
| Study            | Description                                                                 |
|------------------|-----------------------------------------------------------------------------|
| Kumar 2000       | Participants were migrants from a very low endemicity area.                 |
| Kumar 2004       | No data presented on non-falciparum malaria.                                |
| Kumar 2012       | Not a DTA study.                                                            |
| Kumar 2013       | Not a diagnostic test accuracy study.                                       |
| Kweka 2011       | *P. falciparum* malaria only.                                               |
| Kyabayinze 2008  | No data presented on non-falciparum malaria.                                |
| Labbé 2001       | No data presented on non-falciparum malaria.                                |
| Lee 1999         | Some participants did not have symptoms of malaria.                         |
| Lee 2008         | Participants were soldiers usually residing in non-endemic areas.           |
| Lee 2011         | Positive and negative blood samples selected for the study.                 |
| Lema 1999        | Some participants were attending for follow-up of a previously diagnosed and treated case of malaria |
| Lepère 2004      | Not a DTA study.                                                            |
| Lim 2001         | Half the participants had malaria confirmed by microscopy before enrolment |
| Llanos Zavalaga 2000 | Not a DTA study.                    |
| Llanos-Zavalaga 2002 | Non-English language.            |
| Mahajan 2000     | Participants were hospital inpatients.                                      |
| Makler 1998      | Review or narrative.                                                        |
| Makler 2009      | Review or narrative.                                                        |
| Malik 2004       | Study was based at a tertiary referral centre with a high percentage of patients with complicated malaria |
| Mankhambo 2002   | Most participants did not have symptoms of malaria.                         |
| Mason 2002       | Some participants did not have symptoms of malaria.                         |
| Mawili-Mboumba 2010 | *P. falciparum* malaria only.                        |
| Mayxay 2004      | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
### (Continued)

| Reference      | Description                                                                 |
|----------------|------------------------------------------------------------------------------|
| Mboera 2006a   | No data presented on non-falciparum malaria.                                |
| McCutchan 2008 | Review or narrative.                                                        |
| McMorrow 2010  | *P. falciparum* malaria only.                                               |
| Meena 2009     | Participants were all hospital inpatients.                                  |
| Menan 1996     | Not a study of malaria RDTs.                                                 |
| Mendiratta 2006| No data presented on non-falciparum malaria.                                |
| Mendoza 2007   | Report does not contain enough information to assess eligibility             |
| Mendoza 2013   | Report does not contain enough information to assess eligibility             |
| Mengesha 1999  | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Mens 2007      | No data presented on non-falciparum malaria.                                |
| Mens 2010      | RDT evaluated is not an immunochromatographic test.                         |
| Metzger 2008   | Participants were recruited by active case finding.                         |
| Metzger 2009   | Not a DTA study.                                                            |
| Mharakurwa 1997a| Participants had all been recently treated for malaria.                     |
| Mharakurwa 1997b| No data presented on non-falciparum malaria.                                |
| Miantusasila 2012| *P. falciparum* malaria only.                                               |
| Mikhail 2011   | Positive and negative blood samples selected for the study.                 |
| Miller 2001    | Letter.                                                                     |
| Miller 2008    | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Mills 1999     | Participants were travellers returning from endemic to non-endemic areas    |
| Mills 2007     | Report does not contain enough information to assess eligibility             |
| Mills 2010     | *P. falciparum* malaria only.                                               |
| Mills 2010a    | *P. falciparum* malaria only.                                               |
Minja 2012 | Not all participants had symptoms of malaria: prospective cohort of pregnant women
---|---
Minodier 2005 | Review or narrative.
Mishra 1999 | Not a consecutive sample; comprised a malaria positive group by microscopy and negative control groups
Mishra 2007 | Report did not contain enough information to assess eligibility
Mohanty 1999 | Report did not contain enough information to assess eligibility
Mohapatra 1996 | No data presented on non-falciparum malaria.
Montoya 2008 | Non-English language.
Moody 2000 | Participants were travellers returning from endemic to non-endemic areas
Moody 2002a | Review or narrative.
Moody 2002b | RDTs tested on artificially cultured blood samples.
Moonasar 2007 | Not a DTA study.
Moonasar 2009 | No data presented on non-falciparum malaria.
Morankar 2011 | *P. falciparum* malaria only.
Moulin 2009 | Review or narrative.
Msellem 2009 | No data presented on non-falciparum malaria.
Mtove 2011 | *P. falciparum* malaria only.
Mueller 2007 | Participants not representative of people presenting to ambulatory care setting with symptoms of malaria
Muhindo 2012 | No data presented on non-falciparum malaria.
Munier 2009 | Report does not contain enough information to assess eligibility
Murahwa 1999 | No data presented on non-falciparum malaria.
Murray 2003 | Review or narrative.
Murray 2008 | Review or narrative.
Mwanza 2005 | No data presented on non-falciparum malaria.
Myjak 2004 | Participants were travellers returning from endemic to non-endemic areas
| Study          | Findings                                                                 |
|---------------|--------------------------------------------------------------------------|
| Naing 2002a   | No data presented on non-falciparum malaria.                              |
| Nema 2005     | All participants were positive for malaria by microscopy.                 |
| Neumann 2008  | Most participants did not have symptoms of malaria.                      |
| Nicastrī 2009a| No data presented on non-falciparum malaria.                              |
| Nigussie 2008 | No data presented on non-falciparum malaria.                              |
| Nkromah 2010  | RDT evaluated is not an immunochromatographic test.                      |
| Nkromah 2011  | *P. falciparum* malaria only: Only 2 cases of non-falciparum malaria (263 study participants) |
| Nour 2011     | Not enough information presented to extract numbers of true positives, false positives, true negatives and false negatives |
| Nwuba 2001    | No data presented on non-falciparum malaria.                              |
| Nyunt 2013    | Not a DTA study: all participants had positive blood slide for *P. falciparum* |
| Ochola 2006   | Review or narrative.                                                      |
| Omar 1999     | No data presented on non-falciparum malaria.                              |
| OMS 1999      | Not a DTA study.                                                          |
| Onile 2005    | Review or narrative.                                                      |
| Osman 2010    | Less than one percent of the malaria detected was *P. vivax*.             |
| Ouattara 2011 | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives for individual malaria species (mainly *P. falciparum* but numbers not provided). |
| Ozbilge 2006  | Not an immunochromatographic test.                                       |
| Pabon 2007    | Non-English language.                                                     |
| Pakalapati 2013| Unable to extract data on numbers of true positives, false positive, true negatives and false negatives |
| Palmer 1998   | Report did not contain enough information to assess eligibility.          |
| Palmer 1999   | All participants were positive for malaria by microscopy.                 |
| Palmer 2003   | Participants were travellers returning from endemic to non-endemic areas |
| Pammenter 1988| Review or narrative.                                                      |
| Reference       | Description                                                                 |
|-----------------|-----------------------------------------------------------------------------|
| Pandey 1995     | Review or narrative.                                                        |
| Pandya 2001     | No data presented on non-falciparum malaria.                                |
| Park 2003       | Not a consecutive sample; included a known malaria group and negative control group by microscopy |
| Park 2006       | Written in Korean only.                                                     |
| Parra 1991      | Not a DTA study.                                                            |
| Peng 2012       | *P. falciparum* malaria only.                                               |
| Penhalbel 2005  | Not a consecutive sample; included a known malaria group and negative control group by microscopy |
| Peyron 1999     | Review or narrative.                                                        |
| Phommanivong 2010 | Not a DTA study.                                                               |
| Pica 2005       | Review or narrative.                                                        |
| Pieroni 1998    | Participants were travellers returning from endemic to non-endemic areas    |
| Pinto 1999      | All participants had previous tested negative for malaria and had symptoms that meant complicated malaria could not be ruled out |
| Piper 1999      | Half the participants lived in non-endemic areas.                           |
| Pividal 1994    | Not a DTA study.                                                            |
| Planche 2001    | Review or narrative.                                                        |
| Playford 2002   | Participants were travellers returning from endemic to non-endemic areas    |
| Popov 2000      | Non-English language.                                                       |
| Popov 2004      | Non-English language.                                                       |
| Premji 1994     | Participants did not have symptoms of malaria.                              |
| Prou 1988       | Not an immunochromatographic test.                                          |
| Proux 2001      | Majority of participants did not have symptoms of malaria.                  |
| Pérez 2007      | Review or narrative.                                                        |
| Quintana 1998   | Report did not contain enough information to assess eligibility             |
| Reference               | Notes                                |
|------------------------|--------------------------------------|
| Rabinovich 2006        | Non-English language.                |
| Radrianasolo 2007      | Non-English language.                |
| Rahim 2002             | All participants were positive for malaria by microscopy. |
| Rajendran 2006         | Report does not contain enough information to assess eligibility |
| Ramutton 2012          | Participants had severe malaria.     |
| Ratnawati 2008         | Many participants were recruited by active case finding. |
| Ratsimbasoa 2012       | *P. falciparum* malaria only.        |
| Rehli 2004             | Non-English language.                |
| Reyburn 2007           | Not a DTA study.                     |
| Ricci 2000             | Participants were travellers returning from endemic to non-endemic areas |
| Richardson 2002        | Participants were travellers returning from endemic to non-endemic areas |
| Richter 2004a          | Review or narrative.                 |
| Richter 2004b          | Participants were travellers returning from endemic to non-endemic areas |
| Rimón 2003             | No data presented on non-falciparum malaria. |
| Roche 1995             | Not an immunochromatographic test.   |
| Rodríguez-Iglesias 2005| Review or narrative.                 |
| Rodulfo 2007           | Some of the participants did not have symptoms of malaria. |
| Rolland 2006           | Not a DTA study.                     |
| Rosenthal 2012         | Not a DTA study: editorial.          |
| Rubio 2001             | Participants were travellers returning from endemic to non-endemic areas |
| Runsewe-Abiodun 2012   | Not enough information presented to absolute numbers of true positives, true negatives, false positives and false negatives |
| Ryan 2002              | Not a DTA study.                     |
| Samal 1998             | Not an immunochromatographic test.   |
| Study                  | Notes                                                                 |
|-----------------------|-----------------------------------------------------------------------|
| Saranya 2003          | Review or narrative.                                                  |
| Sayang 2009           | No data presented on non-falciparum malaria.                         |
| Schachterle 2011      | *P. falciparum* only.                                                |
| Schmidt 2003          | Review or narrative.                                                 |
| Schmidt 2011          | Only participants with positive *P. falciparum* malaria slides were included. |
| Seidahmed 2008        | Not a DTA study.                                                     |
| Senn 2012             | Not a diagnostic test accuracy study: blood slide was performed to assess treatment outcome |
| Sezibera 2009         | Not a DTA study.                                                     |
| Shah 2004             | All participants were positive for malaria by microscopy.             |
| Shaikh 2013           | Does not differentiate malaria parasitaemia by species.              |
| Shakya 2012           | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Shamsi 1999           | Report did not contain enough information to assess eligibility       |
| Sharma 1999           | No data presented on non-falciparum malaria.                         |
| Sharma 2008           | Some participants did not have symptoms of malaria.                   |
| She 2007              | Not undertaken in a malaria endemic area.                             |
| Shenoi 1996           | Report did not contain enough information to assess eligibility       |
| Shiff 1993            | Some participants did not have symptoms of malaria.                   |
| Shillcutt 2008        | Not a DTA study.                                                     |
| Shirayama 2008        | Not a DTA study.                                                     |
| Shujatullah 2006      | Participants had severe or complicated malaria.                      |
| Shujatullah 2009      | Participants were hospital inpatients.                               |
| Singer 2004           | Most participants did not have symptoms of malaria.                  |
| Singh 1997a           | No data presented on non-falciparum malaria.                         |
(Continued)

| Study          | Description provided                                      |
|----------------|---------------------------------------------------------|
| Singh 1997b    | No data presented on non-falciparum malaria.            |
| Singh 2000b    | Some participants did not have symptoms of malaria.     |
| Singh 2000c    | No data presented on non-falciparum malaria.            |
| Singh 2001     | Participants were recruited by active case finding.    |
| Singh 2002a    | Most participants did not have symptoms of malaria.     |
| Singh 2002b    | All participants were positive for malaria by microscopy.|
| Singh 2004a    | Participants had severe or complicated malaria.        |
| Singh 2005a    | Most participants did not have symptoms of malaria.     |
| Singh 2005b    | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Singh 2005c    | Some participants did not have symptoms of malaria.     |
| Singh 2007     | Most participants did not have symptoms of malaria.     |
| Singh 2013     | Participants selected through active case detection.   |
| Skarbinski 2009| Not a DTA study.                                        |
| Smego 2000     | Review or narrative.                                   |
| Sotimchen 2007 | Most participants did not have symptoms of malaria.     |
| Soto Tarazona 2004 | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Srinivasan 2000| Participants were travellers returning from endemic to non-endemic areas |
| Stauffer 2005  | Participants were refugees from an endemic to a non-endemic country |
| Stauffer 2006  | Participants were travellers returning from endemic to non-endemic areas |
| Stauffer 2009  | Participants were all travellers returning from endemic to a non-endemic area |
| Stephens 1999  | No data presented on non-falciparum malaria.            |
| Stow 1999      | No data presented on non-falciparum malaria.            |
| Study               | Description                                                                 |
|---------------------|-----------------------------------------------------------------------------|
| Strom 2013          | No cases of non-falciparum malaria.                                         |
| Stürenburg 2009     | Review or narrative.                                                        |
| Surpur 2010         | Data not presented for *P. falciparum* and *P. vivax* separately.           |
| Susi 2005           | Participants were all travellers returning from an endemic to a non-endemic area |
| Swarthout 2007      | All participants were positive for malaria by microscopy.                    |
| Tagbo 2007          | No data presented on non-falciparum malaria.                                |
| Tagbor 2008         | Most participants did not have symptoms of malaria.                         |
| Tahar 2013          | *P. falciparum* malaria only: only 4 cases of non-falciparum malaria (179 participants) |
| Tarimo 2001         | Unable to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Taylor 2002         | All participants were positive for malaria by microscopy.                    |
| Tekeste 2012        | *P. falciparum* malaria only.                                               |
| Tham 1999           | Participants were all travellers returning from an endemic to a non-endemic area |
| Thepsamarn 1997     | All participants were positive for malaria by microscopy.                    |
| Tietche 1996        | Not a DTA study.                                                            |
| Tjitra 2001a        | All participants were positive for malaria by microscopy.                    |
| Tjitra 2001b        | All participants were positive for malaria by microscopy.                    |
| Trachslar 1999      | Not a DTA study.                                                            |
| Uguen 1995          | Participants were travellers returning from endemic to non-endemic areas    |
| Uneke 2008a         | Review or narrative.                                                        |
| Uneke 2008b         | Not a DTA study.                                                            |
| Uzochukwu 2009      | No data presented on non-falciparum malaria.                                |
| Valecha 1998        | Report does not contain enough information to assess eligibility             |
| Valecha 2002        | Participants were recruited by active case finding.                         |
| Year       | Details                                                   |
|------------|-----------------------------------------------------------|
| Valéa 2009 | No data presented on non-falciparum malaria.             |
| Van den Ende 1998 | Participants were travellers returning from endemic to non-endemic areas |
| Van der Palen 2009 | Participants were travellers returning from endemic to non-endemic areas |
| Van Dijk 2009 | Participants were travellers returning from an endemic to a non-endemic area |
| van Hellemont 2009 | Not a DTA study.                                   |
| VanderJagt 2005 | Most participants had no symptoms of malaria.              |
| Venkatesh 2007 | Participants had severe or complicated malaria.          |
| Verlé 1996 | No data presented on non-falciparum malaria.             |
| Voller 1993 | Review or narrative.                                    |
| Waltz 2007 | Review or narrative.                                    |
| Wang J-Y 2007 | Not a commercial test kit.                              |
| Wanji 2008 | Participants did not have symptoms of malaria.           |
| WHO 1996 | Review or narrative.                                   |
| Wiese 2006 | Participants were travellers returning from endemic to non-endemic areas |
| Willcox 2009 | No data presented on non-falciparum malaria.             |
| Williams 2008 | Not a DTA study.                                   |
| Wilson 2013 | Review or narrative.                                   |
| Win 2001 | Review or narrative.                                   |
| Wolday 2001 | No data presented on non-falciparum malaria.             |
| Wongsrichanalai 1999 | No data presented on non-falciparum malaria.            |
| Wongsrichanalai 2001 | Review or narrative.                               |
| Wongsrichanalai 2007 | Review or narrative.                               |
| Woyessa 2013 | Participants recruited through active case detection (population survey) |
| Wu 2005 | Not an immunochromatographic RDT kit.                   |
| Reference       | Issue                                                                 |
|-----------------|----------------------------------------------------------------------|
| Yadav 1997      | No data presented on non-falciparum malaria.                         |
| Yadav 2012      | Not enough information presented to assess eligibility (not clear where participants presented with symptoms) |
| Yavo 2002       | No data presented on non-falciparum malaria.                         |
| Zakai 2003      | Review or narrative.                                                 |
| Zerpa 2007      | Not able to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives |
| Zheng 1999      | Non-English language.                                                |
| Zhu 1998        | Non-English language.                                                |
| Zikusooka 2008  | Not a DTA study.                                                     |
| Zurovac 2008    | Not a DTA study.                                                     |
**DATA**

Presented below are all the data for all of the tests entered into the review.

**Tests. Data tables by test**

| Test | No. of studies | No. of participants |
|------|----------------|---------------------|
| 1 Non-falciparum species only, microscopy, Type 2, ICT Combo Cassette | 1 | 2383 |
| 2 Non-falciparum species only, microscopy, Type 2, ICT Malaria Pf/Pv | 7 | 3151 |
| 3 Non-falciparum species only, microscopy, Type 2, NOW Malaria ICT | 1 | 246 |
| 4 Non-falciparum species only, microscopy, Type 2, Malascan | 1 | 372 |
| 5 Non-falciparum species only, microscopy, Type 2, VIKIA Ag Pf/Pan | 1 | 727 |
| 6 Non-falciparum species only, microscopy, Type 2 (All) | 11 | 6879 |
| 7 Non-falciparum species only, microscopy, Type 3, Parascreen | 14 | 5407 |
| 8 Non-falciparum species only, microscopy, Type 3, CareStart Pf/Pan | 4 | 3544 |
| 9 Non-falciparum species only, microscopy, Type 3, SD Malaria Antigen Bioline | 4 | 3769 |
| 10 Non-falciparum species only, microscopy, Type 3, First Response Malaria Combo | 2 | 663 |
| 11 Non-falciparum species only, microscopy, Type 3, One Step Malaria Pf/Pan | 1 | 606 |
| 12 Non-falciparum species only, microscopy, Type 3 (All) | 23 | 11234 |
| 13 Non-falciparum species only, microscopy, Type 4, OptiMAL | 6 | 1843 |
| 14 Non-falciparum species only, microscopy, Type 4, OptiMAL-IT | 4 | 1987 |
| 15 Non-falciparum species only, microscopy, Type 4, Carestart | 1 | 195 |
| 16 Non-falciparum species only, microscopy, Type 4 (All) | 10 | 3831 |
| Test                                      | Value | Notes              |
|-------------------------------------------|-------|--------------------|
| 17 Non-falciparum species only, microscopy, Other Type, Malariagen Malaria | 1     | 262                |
| 18 Non-falciparum species only, PCR, Type 3, CareStart Pf/Pan | 1     | 178                |
| 19 Non-falciparum species only, PCR, Type 3, Parascreen | 2     | 659                |
| 20 Non-falciparum species only, PCR, Type 3, One Step Malaria Pf/Pan | 1     | 606                |
| 21 Non-falciparum species only, PCR, Type 3, SD Malaria Antigen Bioline | 1     | 196                |
| 22 Non-falciparum species only, PCR, Type 3 (All) | 5     | 1639               |
| 23 Non-falciparum species only, PCR, Type 4, OptiMAL (All) | 1     | 313                |
| 24 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Carestart Pf/Pv (All) | 3     | 2000               |
| 25 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Biotech Malaria Pf/Pv | 1     | 250                |
| 26 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Falcivax | 2     | 710                |
| 27 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Onsite Pf/Pv | 2     | 710                |
| 28 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Pf/Pv Malaria Device | 1     | 350                |
| 29 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH (All) | 8     | 3682               |
| 30 *P. vivax*, PCR, Pf HRP-2 and Pv pLDH, Falcivax | 1     | 338                |
| 31 *P. vivax*, PCR, Pf HRP-2 and Pv pLDH, OnSite Pf/Pv | 1     | 338                |
| 32 *P. vivax*, PCR, Pf HRP-2 and Pv pLDH, Pf/Pv Malaria Device | 1     | 350                |
| 33 *P. vivax*, PCR, Pf HRP-2 and Pv pLDH (All) | 2     | 688                |
| 34 *P. vivax*, PCR, Type 6, PALUTOP (All) | 1     | 313                |
### Test 1. Non-falciparum species only, microscopy, Type 2, ICT Combo Cassette.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 1 Non-falciparum species only, microscopy, Type 2, ICT Combo Cassette

| Study     | TP   | FP   | FN   | TN   | Sensitivity        | Specificity        |
|-----------|------|------|------|------|--------------------|--------------------|
| Ashton 2010 | 209  | 85   | 37   | 2052 | 0.85 [0.80, 0.89]  | 0.96 [0.95, 0.97]  |

### Test 2. Non-falciparum species only, microscopy, Type 2, ICT Malaria Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 2 Non-falciparum species only, microscopy, Type 2, ICT Malaria Pf/Pv

| Study         | TP   | FP   | FN   | TN   | Sensitivity        | Specificity        |
|---------------|------|------|------|------|--------------------|--------------------|
| Bell 2001a    | 32   | 2    | 16   | 300  | 0.67 [0.52, 0.80]  | 0.99 [0.98, 1.00]  |
| Bell 2001b    | 25   | 9    | 6    | 73   | 0.81 [0.63, 0.93]  | 0.89 [0.80, 0.95]  |
| Fernando 2004 | 70   | 2    | 29   | 227  | 0.71 [0.61, 0.79]  | 0.99 [0.97, 1.00]  |
| Harani 2006   | 27   | 10   | 3    | 520  | 0.90 [0.73, 0.98]  | 0.98 [0.97, 0.99]  |
| Singh 2000a   | 34   | 3    | 13   | 294  | 0.72 [0.57, 0.84]  | 0.99 [0.97, 1.00]  |
| Tjitra 1999   | 27   | 27   | 9    | 497  | 0.75 [0.58, 0.88]  | 0.95 [0.93, 0.97]  |
| van den Broek 2006 | 217 | 1    | 74   | 604  | 0.75 [0.69, 0.79]  | 1.00 [0.99, 1.00]  |
**Test 3. Non-falciparum species only, microscopy, Type 2, NOW Malaria ICT.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 3 Non-falciparum species only, microscopy, Type 2, NOW Malaria ICT

| Study              | TP  | FP  | FN  | TN  | Sensitivity       | Specificity       |
|--------------------|-----|-----|-----|-----|-------------------|-------------------|
| Wongsinchanalai 2003 | 59  | 0   | 9   | 178 | 0.87 [0.76, 0.94] | 1.00 [0.98, 1.00] |

**Test 4. Non-falciparum species only, microscopy, Type 2, Malascan.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 4 Non-falciparum species only, microscopy, Type 2, Malascan

| Study   | TP  | FP  | FN  | TN  | Sensitivity       | Specificity       |
|---------|-----|-----|-----|-----|-------------------|-------------------|
| Singh 2010 | 39  | 7   | 18  | 308 | 0.68 [0.55, 0.80] | 0.98 [0.95, 0.99] |

**Test 5. Non-falciparum species only, microscopy, Type 2, VIKIA Ag Pf/Pan.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 5 Non-falciparum species only, microscopy, Type 2, VIKIA Ag Pf/Pan

| Study    | TP  | FP  | FN  | TN  | Sensitivity       | Specificity       |
|----------|-----|-----|-----|-----|-------------------|-------------------|
| Eibach 2013 | 4   | 6   | 1   | 716 | 0.80 [0.28, 0.99] | 0.99 [0.98, 1.00] |
**Test 6. Non-falciparum species only, microscopy, Type 2 (All).**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 6 Non-falciparum species only, microscopy, Type 2 (All)

| Study          | TP   | FP   | FN   | TN   | Sensitivity | Specificity | Sensitivity | Specificity |
|----------------|------|------|------|------|-------------|-------------|-------------|-------------|
| Ashton 2010    | 209  | 85   | 37   | 2052 | 0.85 [0.80, 0.89] | 0.96 [0.95, 0.97] |             |             |
| Bell 2001a     | 32   | 2    | 16   | 300  | 0.67 [0.52, 0.80] | 0.99 [0.98, 1.00] |             |             |
| Bell 2001b     | 25   | 9    | 6    | 73   | 0.81 [0.63, 0.93] | 0.89 [0.80, 0.95] |             |             |
| Eibach 2013    | 4    | 6    | 1    | 716  | 0.80 [0.28, 0.99] | 0.99 [0.98, 1.00] |             |             |
| Fernando 2004  | 70   | 2    | 29   | 227  | 0.71 [0.61, 0.79] | 0.99 [0.97, 1.00] |             |             |
| Harani 2006    | 27   | 10   | 3    | 520  | 0.90 [0.73, 0.98] | 0.98 [0.97, 0.99] |             |             |
| Singh 2000a    | 34   | 3    | 13   | 294  | 0.72 [0.57, 0.84] | 0.99 [0.97, 1.00] |             |             |
| Singh 2010     | 39   | 7    | 18   | 308  | 0.68 [0.55, 0.80] | 0.98 [0.95, 0.99] |             |             |
| Tjitra 1999    | 27   | 27   | 9    | 497  | 0.75 [0.58, 0.88] | 0.95 [0.93, 0.97] |             |             |
| van den Broek 2006 | 217 | 1    | 74   | 604  | 0.75 [0.69, 0.79] | 1.00 [0.99, 1.00] |             |             |
| Wongsrichanalai 2003 | 59   | 0   | 9    | 178  | 0.87 [0.76, 0.94] | 1.00 [0.98, 1.00] |             |             |
Test 7. Non-falciparum species only, microscopy, Type 3, Parascreen.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 7 Non-falciparum species only, microscopy, Type 3, Parascreen

| Study        | TP   | FP   | FN   | TN   | Sensitivity | Specificity | Sensitivity | Specificity |
|--------------|------|------|------|------|-------------|-------------|-------------|-------------|
| Ashton 2010  | 203  | 96   | 43   | 2041 | 0.83 [0.77, 0.87] | 0.96 [0.95, 0.96] |             |             |
| Bendzeu 2010 | 64   | 6    | 19   | 243  | 0.77 [0.67, 0.86] | 0.98 [0.95, 0.99] |             |             |
| Elahi 2013   | 49   | 3    | 5    | 270  | 0.91 [0.80, 0.97] | 0.99 [0.97, 1.00] |             |             |
| Endeshaw 2012a | 3  | 4    | 3    | 190  | 0.50 [0.12, 0.88] | 0.98 [0.95, 0.99] |             |             |
| Endeshaw 2012b | 32 | 4    | 4    | 160  | 0.89 [0.74, 0.97] | 0.98 [0.94, 0.99] |             |             |
| Endeshaw 2012c | 6  | 3    | 5    | 184  | 0.55 [0.23, 0.83] | 0.98 [0.95, 1.00] |             |             |
| Endeshaw 2012d | 2  | 1    | 2    | 195  | 0.50 [0.07, 0.93] | 0.99 [0.97, 1.00] |             |             |
| Endeshaw 2012e | 5  | 7    | 0    | 185  | 1.00 [0.48, 1.00] | 0.96 [0.93, 0.99] |             |             |
| Endeshaw 2012f | 8  | 0    | 0    | 192  | 1.00 [0.63, 1.00] | 1.00 [0.98, 1.00] |             |             |
| Endeshaw 2012g | 3  | 1    | 2    | 192  | 0.60 [0.15, 0.95] | 0.99 [0.97, 1.00] |             |             |
| Endeshaw 2012h | 14 | 0    | 2    | 184  | 0.88 [0.62, 0.98] | 1.00 [0.98, 1.00] |             |             |
| Endeshaw 2012i | 10 | 4    | 0    | 186  | 1.00 [0.69, 1.00] | 0.98 [0.95, 0.99] |             |             |
| Endeshaw 2012j | 4  | 3    | 12   | 181  | 0.25 [0.07, 0.52] | 0.98 [0.95, 1.00] |             |             |
| Singh 2010   | 44   | 6    | 13   | 309  | 0.77 [0.64, 0.87] | 0.98 [0.96, 0.99] |             |             |
### Test 8. Non-falciparum species only, microscopy, Type 3, CareStart Pf/Pan.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 8 Non-falciparum species only, microscopy, Type 3, CareStart Pf/Pan

| Study          | TP   | FP   | FN   | TN   | Sensitivity | Specificity | Sensitivity | Specificity |
|---------------|------|------|------|------|-------------|-------------|-------------|-------------|
| Ashton 2010   | 209  | 77   | 37   | 2060 | 0.85 [0.80, 0.89] | 0.96 [0.96, 0.97] |           |             |
| Eibach 2013   | 3    | 4    | 2    | 718  | 0.60 [0.15, 0.95] | 0.99 [0.99, 1.00] |           |             |
| Moges 2012    | 20   | 4    | 38   | 192  | 0.34 [0.22, 0.48] | 0.98 [0.95, 0.99] |           |             |
| Xiaodong 2013 | 59   | 0    | 6    | 115  | 0.91 [0.81, 0.97] | 1.00 [0.97, 1.00] |           |             |

### Test 9. Non-falciparum species only, microscopy, Type 3, SD Malaria Antigen Bioline.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 9 Non-falciparum species only, microscopy, Type 3, SD Malaria Antigen Bioline

| Study          | TP   | FP   | FN   | TN   | Sensitivity | Specificity | Sensitivity | Specificity |
|---------------|------|------|------|------|-------------|-------------|-------------|-------------|
| Dev 2004      | 5    | 0    | 2    | 23   | 0.71 [0.29, 0.96] | 1.00 [0.85, 1.00] |           |             |
| Kosack 2013   | 454  | 26   | 133  | 1972 | 0.77 [0.74, 0.81] | 0.99 [0.98, 0.99] |           |             |
| Ratsimbasa 2007 | 11  | 4    | 4    | 175  | 0.73 [0.45, 0.92] | 0.98 [0.94, 0.99] |           |             |
| Trouvay 2013  | 111  | 3    | 18   | 828  | 0.86 [0.79, 0.92] | 1.00 [0.99, 1.00] |           |             |
Test 10. Non-falciparum species only, microscopy, Type 3, First Response Malaria Combo.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries.

Test: 10 Non-falciparum species only, microscopy, Type 3, First Response Malaria Combo

| Study   | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|---------|-----|-----|-----|-----|-------------|-------------|
| Bharti 2008 | 34  | 15  | 7   | 235 | 0.83 [0.68, 0.93] | 0.94 [0.90, 0.97] |
| Singh 2010   | 48  | 11  | 9   | 304 | 0.84 [0.72, 0.93] | 0.97 [0.94, 0.98] |

Test 11. Non-falciparum species only, microscopy, Type 3, One Step Malaria Pf/Pan.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries.

Test: 11 Non-falciparum species only, microscopy, Type 3, One Step Malaria Pf/Pan

| Study   | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|---------|-----|-----|-----|-----|-------------|-------------|
| Yan 2013 | 51  | 5   | 22  | 528 | 0.70 [0.58, 0.80] | 0.99 [0.98, 1.00] |
Test 12. Non-falciparum species only, microscopy, Type 3 (All).

**Review:** Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

**Test:** 12 Non-falciparum species only, microscopy, Type 3 (All)

| Study            | TP  | FP  | FN  | TN  | Sensitivity     | Specificity     | Sensitivity     | Specificity     |
|------------------|-----|-----|-----|-----|-----------------|-----------------|-----------------|-----------------|
| Ashton 2010      | 209 | 77  | 37  | 2060| 0.85 [0.80, 0.89]| 0.96 [0.96, 0.97]|                |                 |
| Bendezu 2010     | 64  | 6   | 19  | 243 | 0.77 [0.67, 0.86]| 0.98 [0.95, 0.99]|                |                 |
| Bharti 2008      | 34  | 15  | 7   | 235 | 0.83 [0.68, 0.93]| 0.94 [0.90, 0.97]|                |                 |
| Dev 2004         | 5   | 0   | 2   | 23  | 0.71 [0.29, 0.96]| 1.00 [0.85, 1.00]|                |                 |
| Eibach 2013      | 3   | 4   | 2   | 71  | 0.60 [0.15, 0.95]| 0.99 [0.99, 1.00]|                |                 |
| Elahi 2013       | 49  | 3   | 5   | 270 | 0.91 [0.80, 0.97]| 0.99 [0.97, 1.00]|                |                 |
| Endeshaw 2012a   | 3   | 4   | 3   | 190 | 0.50 [0.12, 0.88]| 0.98 [0.95, 0.99]|                |                 |
| Endeshaw 2012b   | 2   | 4   | 4   | 160 | 0.89 [0.74, 0.97]| 0.98 [0.94, 0.99]|                |                 |
| Endeshaw 2012c   | 6   | 3   | 5   | 184 | 0.55 [0.23, 0.83]| 0.98 [0.95, 1.00]|                |                 |
| Endeshaw 2012d   | 2   | 1   | 2   | 195 | 0.50 [0.07, 0.93]| 0.99 [0.97, 1.00]|                |                 |
| Endeshaw 2012e   | 5   | 7   | 0   | 185 | 1.00 [0.48, 1.00]| 0.96 [0.93, 0.99]|                |                 |
| Endeshaw 2012f   | 8   | 0   | 0   | 192 | 1.00 [0.63, 1.00]| 1.00 [0.98, 1.00]|                |                 |
| Endeshaw 2012g   | 3   | 1   | 2   | 192 | 0.60 [0.15, 0.95]| 0.99 [0.97, 1.00]|                |                 |
| Endeshaw 2012h   | 14  | 0   | 2   | 184 | 0.88 [0.62, 0.98]| 1.00 [0.98, 1.00]|                |                 |
| Endeshaw 2012i   | 10  | 4   | 0   | 186 | 1.00 [0.69, 1.00]| 0.98 [0.95, 0.99]|                |                 |
| Endeshaw 2012j   | 4   | 3   | 12  | 181 | 0.25 [0.07, 0.52]| 0.98 [0.95, 1.00]|                |                 |
| Kosack 2013      | 454 | 26  | 133 | 1972| 0.77 [0.74, 0.81]| 0.99 [0.98, 0.99]|                |                 |
| Moges 2012       | 20  | 4   | 38  | 192 | 0.34 [0.22, 0.48]| 0.98 [0.95, 0.99]|                |                 |
| Ratsimbasoa 2007 | 11  | 4   | 4   | 175 | 0.73 [0.45, 0.92]| 0.98 [0.94, 0.99]|                |                 |
| Singh 2010       | 44  | 6   | 13  | 309 | 0.77 [0.64, 0.87]| 0.98 [0.96, 0.99]|                |                 |
| Trouvay 2013     | 111 | 3   | 18  | 828 | 0.86 [0.79, 0.92]| 1.00 [0.99, 1.00]|                |                 |
| Xiaodong 2013    | 59  | 0   | 6   | 115 | 0.91 [0.81, 0.97]| 1.00 [0.97, 1.00]|                |                 |
| Yan 2013         | 51  | 5   | 22  | 528 | 0.70 [0.58, 0.80]| 0.99 [0.98, 1.00]|                |                 |
**Test 13. Non-falciparum species only, microscopy, Type 4, OptiMAL.**

| Study            | TP | FP | FN | TN  | Sensitivity       | Specificity       | Sensitivity       | Specificity       |
|------------------|----|----|----|-----|-------------------|-------------------|-------------------|-------------------|
| Chayani 2004     | 23 | 2  | 3  | 204 | 0.88 [0.70, 0.98] | 0.99 [0.97, 1.00] |                   |                   |
| Dev 2004         | 26 | 0  | 3  | 111 | 0.90 [0.73, 0.98] | 1.00 [0.97, 1.00] |                   |                   |
| Kolacinski 2004  | 142| 5  | 23 | 328 | 0.86 [0.80, 0.91] | 0.98 [0.97, 1.00] |                   |                   |
| Ratsimbasa 2007  | 15 | 2  | 2  | 175 | 0.88 [0.64, 0.99] | 0.99 [0.96, 1.00] |                   |                   |
| Singh 2003       | 22 | 1  | 0  | 57  | 1.00 [0.85, 1.00] | 0.98 [0.91, 1.00] |                   |                   |
| Valecha 2003     | 173| 16 | 13 | 497 | 0.93 [0.88, 0.96] | 0.97 [0.95, 0.98] |                   |                   |

**Test 14. Non-falciparum species only, microscopy, Type 4, OptiMAL-IT.**

| Study          | TP | FP | FN | TN  | Sensitivity       | Specificity       | Sensitivity       | Specificity       |
|----------------|----|----|----|-----|-------------------|-------------------|-------------------|-------------------|
| Andrade 2010   | 84 | 14 | 0  | 213 | 1.00 [0.96, 1.00] | 0.94 [0.90, 0.97] |                   |                   |
| Metzger 2011   | 52 | 6  | 30 | 426 | 0.63 [0.52, 0.74] | 0.99 [0.97, 0.99] |                   |                   |
| Pattanasin 2003| 56 | 2  | 29 | 179 | 0.66 [0.55, 0.76] | 0.99 [0.96, 1.00] |                   |                   |
| van den Broek 2006 | 256 | 6  | 36 | 598 | 0.88 [0.83, 0.91] | 0.99 [0.98, 1.00] |                   |                   |
Test 15. Non-falciparum species only, microscopy, Type 4, Carestart.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or Plasmodium vivax malaria in endemic countries

Test: 15 Non-falciparum species only, microscopy, Type 4, Carestart

| Study          | TP | FP | FN | TN  | Sensitivity    | Specificity    |
|----------------|----|----|----|-----|----------------|----------------|
| Ratsimbasoa 2007 | 12 | 5  | 3  | 175 | 0.80 [0.52, 0.96] | 0.97 [0.94, 0.99] |

Test 16. Non-falciparum species only, microscopy, Type 4 (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or Plasmodium vivax malaria in endemic countries

Test: 16 Non-falciparum species only, microscopy, Type 4 (All)

| Study          | TP | FP | FN | TN  | Sensitivity    | Specificity    |
|----------------|----|----|----|-----|----------------|----------------|
| Andrade 2010   | 84 | 14 | 0  | 213 | 1.00 [0.96, 1.00] | 0.94 [0.90, 0.97] |
| Chayani 2004   | 23 | 2  | 3  | 204 | 0.88 [0.70, 0.98] | 0.99 [0.97, 1.00] |
| Dev 2004       | 26 | 0  | 3  | 111 | 0.90 [0.73, 0.98] | 1.00 [0.97, 1.00] |
| Kolaczinski 2004 | 142 | 5 | 23 | 328 | 0.86 [0.80, 0.91] | 0.98 [0.97, 1.00] |
| Metzger 2011   | 52 | 6  | 30 | 426 | 0.63 [0.52, 0.74] | 0.99 [0.97, 0.99] |
| Pattanasin 2003| 56 | 2  | 29 | 179 | 0.66 [0.55, 0.76] | 0.99 [0.96, 1.00] |
| Ratsimbasoa 2007 | 12 | 5  | 3  | 175 | 0.80 [0.52, 0.96] | 0.97 [0.94, 0.99] |
| Singh 2003     | 22 | 1  | 0  | 57  | 1.00 [0.85, 1.00] | 0.98 [0.91, 1.00] |
| Valecha 2003   | 173| 16 | 13 | 497 | 0.93 [0.88, 0.96] | 0.97 [0.95, 0.98] |
| van den Broek 2006 | 256 | 6 | 36 | 598 | 0.88 [0.83, 0.91] | 0.99 [0.98, 1.00] |
**Test 17. Non-falciparum species only, microscopy, Other Type, Malariagen Malaria.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 17 Non-falciparum species only, microscopy, Other Type, Malariagen Malaria

| Study          | TP | FP | FN | TN  | Sensitivity | Specificity |
|----------------|----|----|----|-----|-------------|-------------|
| Selimuzzaman 2010 | 11 | 12 | 1  | 238 | 0.92 [0.62, 1.00] | 0.95 [0.92, 0.97] |

**Test 18. Non-falciparum species only, PCR, Type 3, CareStart Pf/Pan.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 18 Non-falciparum species only, PCR, Type 3, CareStart Pf/Pan

| Study          | TP | FP | FN | TN  | Sensitivity | Specificity |
|----------------|----|----|----|-----|-------------|-------------|
| Xiaodong 2013 | 59 | 0  | 6  | 113 | 0.91 [0.81, 0.97] | 1.00 [0.97, 1.00] |

**Test 19. Non-falciparum species only, PCR, Type 3, Parascreen.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 19 Non-falciparum species only, PCR, Type 3, Parascreen

| Study          | TP | FP | FN | TN  | Sensitivity | Specificity |
|----------------|----|----|----|-----|-------------|-------------|
| Bendeuz 2010 | 67 | 3  | 21 | 241 | 0.76 [0.66, 0.85] | 0.99 [0.96, 1.00] |
| Elahi 2013    | 49 | 3  | 5  | 270 | 0.91 [0.80, 0.97] | 0.99 [0.97, 1.00] |
**Test 20. Non-falciparum species only, PCR, Type 3, One Step Malaria Pf/Pan.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 20 Non-falciparum species only, PCR, Type 3, One Step Malaria Pf/Pan

| Study       | TP  | FP  | FN  | TN  | Sensitivity  | Specificity        | Sensitivity | Specificity |
|-------------|-----|-----|-----|-----|--------------|---------------------|-------------|-------------|
| Yan 2013    | 51  | 15  | 20  | 520 | 0.72 [0.60, 0.82] | 0.97 [0.95, 0.98] | 0.2 0.4 0.6 0.8 | 1 0 0.2 0.4 0.6 0.8 1 |

**Test 21. Non-falciparum species only, PCR, Type 3, SD Malaria Antigen Bioline.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 21 Non-falciparum species only, PCR, Type 3, SD Malaria Antigen Bioline

| Study       | TP  | FP  | FN  | TN  | Sensitivity  | Specificity        | Sensitivity | Specificity |
|-------------|-----|-----|-----|-----|--------------|---------------------|-------------|-------------|
| Ratsimbasoa 2008 | 14  | 1   | 8   | 173 | 0.64 [0.41, 0.83] | 0.99 [0.97, 1.00] | 0 0.2 0.4 0.6 0.8 | 1 0 0.2 0.4 0.6 0.8 1 |
**Test 22. Non-falciparum species only, PCR, Type 3 (All).**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum *Plasmodium vivax* malaria in endemic countries

Test: 22 Non-falciparum species only, PCR, Type 3 (All)

| Study               | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|---------------------|-----|-----|-----|-----|-------------|-------------|
| Bendezu 2010        | 67  | 3   | 21  | 241 | 0.76 [0.66, 0.85] | 0.99 [0.96, 1.00] |
| Elahi 2013          | 49  | 3   | 5   | 270 | 0.91 [0.80, 0.97] | 0.99 [0.97, 1.00] |
| Ratsimbasoa 2008    | 14  | 1   | 8   | 173 | 0.64 [0.41, 0.83] | 0.99 [0.97, 1.00] |
| Xiaodong 2013       | 59  | 0   | 6   | 113 | 0.91 [0.81, 0.97] | 1.00 [0.97, 1.00] |
| Yan 2013            | 51  | 15  | 20  | 520 | 0.72 [0.60, 0.82] | 0.97 [0.95, 0.98] |

**Test 23. Non-falciparum species only, PCR, Type 4, OptiMAL (All).**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum *Plasmodium vivax* malaria in endemic countries

Test: 23 Non-falciparum species only, PCR, Type 4, OptiMAL (All)

| Study               | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|---------------------|-----|-----|-----|-----|-------------|-------------|
| Rakotonirina 2008   | 15  | 6   | 2   | 290 | 0.88 [0.64, 0.99] | 0.98 [0.96, 0.99] |
### Test 24. *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Carestar Pf/Pv (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 24 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Carestar Pf/Pv (All)

| Study      | TP  | FP  | FN  | TN  | Sensitivity | Specificity | Sensitivity | Specificity |
|------------|-----|-----|-----|-----|-------------|-------------|-------------|-------------|
| Chanie 2011| 25  | 4   | 0   | 1063| 1.00 [ 0.86, 1.00 ] | 1.00 [ 0.99, 1.00 ] |            |             |
| Mekonnen 2010| 61  | 0   | 3   | 176 | 0.95 [ 0.87, 0.99 ] | 1.00 [ 0.98, 1.00 ] |            |             |
| Sharew 2009| 155 | 9   | 1   | 503 | 0.99 [ 0.96, 1.00 ] | 0.98 [ 0.97, 0.99 ] |            |             |

### Test 25. *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Biotech Malaria Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 25 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Biotech Malaria Pf/Pv

| Study      | TP  | FP  | FN  | TN  | Sensitivity | Specificity | Sensitivity | Specificity |
|------------|-----|-----|-----|-----|-------------|-------------|-------------|-------------|
| Samane 2010| 110 | 0   | 2   | 138 | 0.98 [ 0.94, 1.00 ] | 1.00 [ 0.97, 1.00 ] |            |             |
**Test 26. P. vivax, microscopy, Pf HRP-2 and Pv pLDH, Falcivax.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 26 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Falcivax

| Study     | TP  | FP  | FN  | TN  | Sensitivity | Specificity | Sensitivity | Specificity |
|-----------|-----|-----|-----|-----|-------------|-------------|-------------|-------------|
| Alam 2011 | 19  | 1   | 2   | 316 | 0.90 [0.70, 0.99] | 1.00 [0.98, 1.00] |             |             |
| Singh 2010| 45  | 3   | 23  | 301 | 0.66 [0.54, 0.77] | 0.99 [0.97, 1.00] |             |             |

**Test 27. P. vivax, microscopy, Pf HRp-2 and Pv pLDH, Onsite Pf/Pv.**

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

Test: 27 *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Onsite Pf/Pv

| Study     | TP  | FP  | FN  | TN  | Sensitivity | Specificity | Sensitivity | Specificity |
|-----------|-----|-----|-----|-----|-------------|-------------|-------------|-------------|
| Alam 2011 | 19  | 4   | 2   | 313 | 0.90 [0.70, 0.99] | 0.99 [0.97, 1.00] |             |             |
| Mohan 2012| 71  | 4   | 2   | 295 | 0.97 [0.90, 1.00] | 0.99 [0.97, 1.00] |             |             |
### Test 28. *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH, Pf/Pv Malaria Device.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

| Study   | TP  | FP  | FN  | TN  | Sensitivity       | Specificity   |
|---------|-----|-----|-----|-----|-------------------|---------------|
| Yan 2013| 45  | 5   | 16  | 284 | 0.74 [0.61, 0.84] | 0.98 [0.96, 0.99] |

### Test 29. *P. vivax*, microscopy, Pf HRP-2 and Pv pLDH (All).

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

| Study   | TP  | FP  | FN  | TN  | Sensitivity       | Specificity   |
|---------|-----|-----|-----|-----|-------------------|---------------|
| Alam 2011| 19  | 1   | 2   | 316 | 0.90 [0.70, 0.99] | 1.00 [0.98, 1.00] |
| Chanie 2011| 25  | 4   | 0   | 1063 | 1.00 [0.86, 1.00] | 1.00 [0.99, 1.00] |
| Mekonnen 2010| 61  | 0   | 3   | 176 | 0.95 [0.87, 0.99] | 1.00 [0.98, 1.00] |
| Mohon 2012| 71  | 4   | 2   | 295 | 0.97 [0.90, 1.00] | 0.99 [0.97, 1.00] |
| Samane 2010| 110 | 0   | 2   | 138 | 0.98 [0.94, 1.00] | 1.00 [0.97, 1.00] |
| Sharew 2009| 155 | 9   | 1   | 503 | 0.99 [0.96, 1.00] | 0.98 [0.97, 0.99] |
| Singh 2010| 45  | 3   | 23  | 301 | 0.66 [0.54, 0.77] | 0.99 [0.97, 1.00] |
| Yan 2013| 45  | 5   | 16  | 284 | 0.74 [0.61, 0.84] | 0.98 [0.96, 0.99] |
### Test 30. P. vivax, PCR, Pf HRP-2 and Pv pLDH, Falcivax.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

| Study   | TP | FP | FN | TN | Sensitivity     | Specificity     | Sensitivity     | Specificity     |
|---------|----|----|----|----|-----------------|-----------------|-----------------|-----------------|
| Alam 2011 | 20 | 0  | 6  | 312 | 0.77 [0.56, 0.91] | 1.00 [0.99, 1.00] |

### Test 31. P. vivax, PCR, Pf HRP-2 and Pv pLDH, OnSite Pf/Pv.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

| Study   | TP | FP | FN | TN | Sensitivity     | Specificity     | Sensitivity     | Specificity     |
|---------|----|----|----|----|-----------------|-----------------|-----------------|-----------------|
| Alam 2011 | 20 | 3  | 6  | 309 | 0.77 [0.56, 0.91] | 0.99 [0.97, 1.00] |

### Test 32. P. vivax, PCR, Pf HRP-2 and Pv pLDH, Pf/Pv Malaria Device.

Review: Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries

| Study   | TP | FP | FN | TN | Sensitivity     | Specificity     | Sensitivity     | Specificity     |
|---------|----|----|----|----|-----------------|-----------------|-----------------|-----------------|
| Yan 2013 | 43 | 7  | 30 | 270 | 0.59 [0.47, 0.70] | 0.97 [0.95, 0.99] |
**Test 33.** \( \text{P. vivax, PCR, Pf HRP-2 and Pv pLDH (All)}. \)

**Review:** Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or \textit{Plasmodium vivax} malaria in endemic countries

**Test:** 33 \( \text{P. vivax, PCR, Pf HRP-2 and Pv pLDH (All)} \)

| Study       | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|-------------|-----|-----|-----|-----|-------------|-------------|
| Alam 2011   | 20  | 3   | 6   | 309 | 0.77 [0.56, 0.91] | 0.99 [0.97, 1.00] |
| Yan 2013    | 43  | 7   | 30  | 270 | 0.59 [0.47, 0.70] | 0.97 [0.95, 0.99] |

**Test 34.** \( \text{P. vivax, PCR, Type 6, PALUTOP (All)}. \)

**Review:** Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or \textit{Plasmodium vivax} malaria in endemic countries

**Test:** 34 \( \text{P. vivax, PCR, Type 6, PALUTOP (All)} \)

| Study       | TP  | FP  | FN  | TN  | Sensitivity | Specificity |
|-------------|-----|-----|-----|-----|-------------|-------------|
| Rakotonirina 2008 | 19 | 0 | 2 | 292 | 0.90 [0.70, 0.99] | 1.00 [0.99, 1.00] |

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or \textit{Plasmodium vivax} malaria in endemic countries (Review)
### Table 1. Types of malaria RDTs by antigen combination and parasite species detected

| Type of test | Antigen combinations | Possible results |
|--------------|----------------------|------------------|
| Type 1       | HRP-2 (*P. falciparum* specific) | No Pf; Pf; invalid |
| Type 2       | HRP-2 (*P. falciparum* specific) and aldolase (pan-specific) | No malaria; Pf or mixed; Pv, Pf, or Pm; invalid |
| Type 3       | HRP-2 (*P. falciparum* specific) and pLDH (pan-specific) | No malaria; Pf or mixed; Pv, Pf, or Pm; invalid |
| Type 4       | pLDH (*P. falciparum* specific) and pLHD (pan-specific) | No malaria; Pf or mixed; Pv, Pf, or Pm; invalid |
| Type 5       | pLDH (*P. falciparum* specific) and pLHD (*P. vivax*-specific) | No malaria; Pf; Pv; Pf and Pv; invalid |
| Type 6       | HRP-2 (*P. falciparum* specific), pLHD (pan-specific) and pLDH (*P. vivax* specific) | No malaria; Pf and Pv ± Po and/or Pm; Pf ± Po and/or Pm; Pv ± Po or Pm; Po or Pm; invalid |
| Type 7       | Aldolase (pan-specific) | No malaria; Pf, Pv, Po, or Pm; invalid |
| Other        | HRP-2 (*P. falciparum* specific) and pLDH (*P. vivax*-specific) | No malaria; Pf; Pv; Pf and Pv; invalid |

### Table 2. Malaria ‘zones’ by endemic parasite species and type of test appropriate for each

| Zone | Endemic malaria parasites | Geographic area | Appropriate test type |
|------|----------------------------|-----------------|-----------------------|
| 1    | *P. falciparum* only or other species almost always as a mixed infection | Most of sub-Saharan Africa; lowland Papua New Guinea | Tests using HRP-2 to detect *P. falciparum* only (Type 1) |
| 2    | Both *P. falciparum* and *P. vivax*, most commonly as a single species | Asia and the Americas; Ethiopian highlands | Combination RDTs which detect all species and distinguish between *P. falciparum* and *P. vivax* (Types 2 to 6) |
| 3    | Non-falciparum only | Vivax-only areas of East Asia and Central Asia; some highland areas elsewhere | Pan-specific or vivax-specific RDTs (Type 7; Pan-pLDH only; vivax-pLDH only) |
Table 3. Number of studies by RDT type and reference standard

| Type of RDT | Number of study cohorts (test evaluations) by reference standard |
|-------------|------------------------------------------------------------------|
|             | Microscopy | PCR |
| Non-falciparum species in the absence of *P. falciparum* | |
| Type 2      | 11 (11)    | 0 (0) |
| Type 3      | 23 (25)    | 5 (5) |
| Type 4      | 10 (11)    | 1 (1) |
| Other type  | 1 (1)      | 0 (0) |
| *P. vivax*  | |
| Pf HRP2 and Pv pLDH | 8 (9) | 2 (3) |
| Type 6      | 0 (0)      | 1 (1) |

Table 4. False negatives for non-falciparum and *P. vivax* by RDT type

| Study          | Test                  | Number of false negatives | % false negatives indicating 'no malaria' | % false negatives indicating 'P. falciparum' |
|----------------|-----------------------|----------------------------|------------------------------------------|---------------------------------------------|
|                |                       |                            |                                          |                                             |
| Type 2 tests   |                       |                            |                                          |                                             |
| Ashton 2010    | ICT Combo             | 37                         | 22                                       | 78                                          |
| Bell 2001a     | ICT Malaria trial 1   | 16                         | 13                                       | 88                                          |
| Bell 2001b     | ICT Malaria trial 2   | 6                          | 67                                       | 33                                          |
| Fernando 2004  | ICT Malaria Pf/Pv     | 29                         | 100                                      | 0                                           |
| Harani 2006    | ICT Malaria Pf/Pv     | 3                          | 67                                       | 33                                          |
| Singh 2000a    | ICT Malaria Pf/Pv     | 13                         | 62                                       | 38                                          |
| Singh 2010     | Malascan              | 18                         | 67                                       | 33                                          |
| Tjtira 1999    | ICT Malaria Pf/Pv     | 8                          | 75                                       | 25                                          |
| van den Broek 2006 | NOW malaria ICT     | 72                         | 67                                       | 33                                          |
| Wongsrichanalai 2003 | ICT Malaria Pf/Pv | 9                          | 67                                       | 33                                          |
Table 4. False negatives for non-falciparum and *P. vivax* by RDT type  

(Continued)

| Study               | RDT Type          | Median (range) | Pooled estimate (95% CI)* |
|---------------------|-------------------|----------------|---------------------------|
| **Type 3 tests**    |                   |                |                           |
| van den Broek 2006  | OptiMAL-IT        | 34             | 74                        | 26                        |
| Median (range)      |                   |                | 67 (13 to 100)            | 33 (0 to 88)              |
| Pooled estimate (95% CI)* |             | 65 (43 to 81)  | 35 (19 to 57)            |
| **Type 4 tests**    |                   |                |                           |
| Andrade 2010        | OptiMAL-IT        | 0              | 0                         | 0                         |
| Chayani 2004        | OptiMAL           | 3              | 100                       | 0                         |

Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries (Review)  
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### Table 4. False negatives for non-falciparum and *P. vivax* by RDT type

*Continued*

| Study            | RDT Type       | Participants | Malaria cases | Pooled sensitivity (95% CI) (%) | Pooled specificity (95% CI) (%) | Test |
|------------------|----------------|--------------|---------------|---------------------------------|---------------------------------|------|
| Dev 2004         | SD Malaria     | 2            | 100           | 100                             | 0                               |      |
| Kolaczinski 2004 | OptiMAL        | 23           | 100           | 100                             | 0                               |      |
| Metzger 2011     | OptiMAL-IT     | 30           | 100           | 100                             | 0                               |      |
| Pattanasin 2003  | OptiMAL-IT     | 26           | 65            | 35                              |                                  |      |
| Ratsimbasoa 2007 | OptiMAL-IT     | 2            | 100           | 0                               |                                  |      |
| Ratsimbasoa 2007 | Carestart Malaria | 3            | 33            | 67                              |                                  |      |
| Singh 2003       | OptiMAL (field)| 0            | 0             | 0                               |                                  |      |
| Soto Tarazona 2004 | OptiMAL      | 3            | 100           | 0                               |                                  |      |
| Valecha 2003     | OptiMAL        | 13           | 77            | 23                              |                                  |      |

**Median (range)**

| Study            | Pooled sensitivity (95% CI) (%) | Pooled specificity (95% CI) (%) |
|------------------|---------------------------------|---------------------------------|
|                  | 100 (0 to 100)                  | 0 (0 to 67)                     |

*The pooled estimates of the percentage of false negatives indicating ‘no malaria’ and the percentage of false negatives indicating ‘*P. falciparum*’ were computed by using a random effects logistic regression model for Type 2 and Type 3. A fixed effects logistic regression model was used for Type 4. This table shows participants with non-falciparum malaria monoinfection identified by microscopy who were negative by non-falciparum monoinfection by RDT, by whether the RDT incorrectly identified the participant as not having malaria, or as having *P. falciparum* malaria.

### Table 5. Non-falciparum infections by RDT types verified by microscopy

| RDT Type | Study cohort | Participants | Malaria cases | Pooled sensitivity (95% CI) (%) | Pooled specificity (95% CI) (%) | Test |
|----------|--------------|--------------|---------------|---------------------------------|---------------------------------|------|
| Type 2   | 11           | 6879         | 958           | 78 (73 to 82)                  | 99 (97 to 99)                  | P = 0.008 |
| Type 3   | 23           | 11,234       | 1537          | 78 (69 to 85)                  | 99 (98 to 99)                  |      |
| Type 4   | 10           | 3831         | 986           | 90 (79 to 95)                  | 98 (97 to 99)                  |      |
| Other type | 1            | 262          | 12            | 92 (62 to 100)                 | 95 (92 to 98)                  |      |

*Likelihood ratio test for evidence of a difference in sensitivity or specificity, or both, between Types 2, 3, and 4. Only one test brand (randomly selected) from each cohort is included in the analysis of each type.*
Table 6. Comparisons of RDT types for non-falciparum infections verified by microscopy

| Ratio of sensitivity (95% CI), P value for comparison | Type 2 | Type 3 |
|------------------------------------------------------|--------|--------|
| Ratio of specificity (95% CI), P value for comparison | Studies (participants) | 11 (6879) | 23 (11,234) |
|                                                      | Sensitivity (95% CI) | 78 (73 to 82) | 78 (69 to 84) |
|                                                      | Specificity (95% CI) | 99 (97 to 99) | 99 (98 to 99) |

Type 2

|                  |Studies (participants) | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------|------------------------|----------------------|----------------------|
|                  | 11 (6879)              | 78 (73 to 82)        | 99 (97 to 99)        |
| Type 3

|                  |Studies (participants) | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------|------------------------|----------------------|----------------------|
|                  | 23 (11,234)            | 78 (69 to 84)        | 99 (98 to 99)        |
| Type 4

|                  |Studies (participants) | Sensitivity (95% CI) | Specificity (95% CI) |
|------------------|------------------------|----------------------|----------------------|
|                  | 10 (3831)              | 90 (79 to 95)        | 98 (97 to 99)        |

We computed the ratio of sensitivities and specificities by division of the sensitivity and specificity for the column by the sensitivity and specificity for the row. If the ratio of sensitivities is greater than one, the sensitivity of the test for the column is higher than that for the row; if less than one, the sensitivity of the test in the row is higher than in the column. The same applies to the ratio of specificities.

APPENDICES

Appendix 1. Search strategy

| Search set | MEDLINE       | EMBASE          |
|------------|---------------|-----------------|
| 1          | Exp Malaria[MeSH] | Exp Malaria [Emtree] |
| 2          | Exp Plasmodium [MeSH] | Exp Plasmodium [Emtree] |
| 3          | Malaria ti, ab   | Malaria ti, ab   |
| 4          | 1 or 2 or 3     | 1 or 2 or 3     |
|   |   |   |
|---|---|---|
| 5 | Exp Reagent kits, diagnostics [MeSH] | Exp Diagnostic procedures [Emtree] |
| 6 | rapid diagnos* test* ti, ab | rapid diagnos$ test$ ti, ab |
| 7 | RDT ti, ab | RDT ti, ab |
| 8 | Dipstick* ti, ab | Dipstick$ ti, ab |
| 9 | Rapid diagnos* device* ti, ab | Rapid diagnos$ device$ ti, ab |
| 10 | MRDD ti, ab | MRDD ti, ab |
| 11 | OptiMal ti, ab | OptiMal ti, ab |
| 12 | Binax NOW ti, ab | Binax NOW ti, ab |
| 13 | ParaSight ti, ab | ParaSight ti, ab |
| 14 | Immunochromatograph* ti, ab | Immunochromatography [Emtree] |
| 15 | Antigen detection method* | Antigen detection method$ |
| 16 | Rapid malaria antigen test* | Rapid malaria antigen test$ |
| 17 | Combo card test* ti, ab | Combo card test$ ti, ab |
| 18 | Immunoassay [MeSH] | Immunoassay [Emtree] |
| 19 | Chromatography [MeSH] | Chromatography [Emtree] |
| 20 | Enzyme-linked immunosorbent assay [MeSH] | Enzyme-linked immunosorbent assay [Emtree] |
| 21 | Rapid test* ti, ab | Rapid test$ ti, ab |
| 22 | Card test* ti, ab | Card test$ ti, ab |
| 23 | Rapid AND (detection* or diagnos*) ti, ab | Rapid AND (detection$ or diagnos$) ti, ab |
| 24 | 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 | 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 |
| 25 | 4 and 19 | 4 and 19 |
| 26 | Limit 20 to Humans | Limit 20 to Human |
### Appendix 2. Data extraction: characteristics of included studies

| Study ID | First author, year of publication. |
|----------|-----------------------------------|
| Clinical features and settings | Presenting signs and symptoms, previous treatments for malaria, clinical setting |
| Participants | Sample size, age, sex, comorbidities or pregnancy, country and locality, *P. falciparum* malaria endemicity, endemic malaria species, average parasite density in microscopy positive cases |
| Study design | Were consecutive patients enrolled retrospectively or prospectively? |
| | Whether the sampling method was consecutive or random, or whether the method was not described but consecutive sampling was most probable |
| | If the study evaluated more than one RDT, how were tests allocated to individuals, or did each individual receive all the tests? |
| Target condition | Malaria parasitaemia. |
| Reference standard | The reference standard test(s) used. |
| | If microscopy was used, who performed it, and where? |
| | If microscopy was used, how many high power fields were looked at? |
| | If microscopy was used, how many observers or repeats were used? |
| | If microscopy was used, how were discrepancies between observers resolved? |
| Index tests | The parasite species the test was designed to detect, the commercial name, and the type of test. Batch numbers if provided. Transport and storage conditions. Details of the test operators, including any special training provided |
| Notes | Source of funding. |

### Appendix 3. Data extraction and criteria for judgement: methodological quality

| Quality indicator | Notes |
|-------------------|-------|
| Was the spectrum of patients representative of the spectrum of patients who will receive the test in practice? | • ‘Yes’ if the inclusion criteria clearly stipulated people attending an ambulatory healthcare setting with symptoms of malaria, and the sampling method was consecutive or random. • ‘No’ if the sample was unrepresentative of people with uncomplicated malaria in general (for example, if the majority of participants also had some other presenting health problem, such as pneumonia). Where a proportion of potential... |
participants were excluded due to recent antimalarial use, well defined comorbidities or pregnancy, the sample could be classed as representative because these groups may also be excluded from testing as normal clinical practice, depending on local policy and practice.

- ‘Unclear’ if the source or characteristics of participants was not adequately described; or if the sampling method was not described.

| Question                                                                 | Yes/No/Unclear                                                                 |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------|
| Is the reference standard likely to correctly identify the target condition? | - ‘Yes’ if microscopy was undertaken by experienced microscopists with adequate laboratory facilities. Laboratory facilities were assumed to be adequate unless the study report indicated otherwise. Slides were viewed by at least two independent observers, either for all slides or for those where there are discordant results between the index and the reference test. At least 100 microscopic fields were viewed before declaring a slide negative.
  - ‘Yes’ if reference standard was PCR.
  - ‘No’ if microscopy was undertaken by insufficiently trained individuals, by one individual only, or in a situation with inadequate equipment, or if they viewed less than 100 microscopic fields before declaring negative.
  - ‘Unclear’ if insufficient information was provided. |
| Is partial verification avoided?                                         | - ‘Yes’ if all participants who received the index test also received the reference test.
  - ‘No’ if not all the participants who received the index test also received the reference test.
  - ‘Unclear’ if insufficient information was provided to assess this. If not all participants received the reference test, we reported how many did not |
| Is differential verification avoided?                                    | - ‘Yes’ if the same reference test was used regardless of the index test results.
  - ‘No’ if different reference tests were used depending on the results of the index test.
  - ‘Unclear’ if insufficient information was provided. If any participants received a different reference test, we reported the reasons stated for this, and how many participants were involved |
| Is incorporation avoided? (the index test does not form part of the reference standard) | This should be ‘Yes’ for all studies, as the reference standard is defined in the inclusion criteria as microscopy or PCR |
| Are the reference standard test results blinded?                        | ‘Yes’ if the person undertaking the reference test did not know the results of the index tests, if the two tests were carried out in different places, or it was clear that the reference test was undertaken and the results recorded before the index test. |
| Question                                                                 | Yes/No/Unclear                                                                                                           |
|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|
| • 'No' if the same person performed both tests, or the results           | • 'Yes' if the person undertaking the index test did not know the results of the reference tests, or if the two tests were carried out in different places, or it was clear that the index test was undertaken and the results recorded before the reference test.  |
| Are the index test results blinded?                                      | • 'No' if the same person performed both tests, or the results of the index tests were known to the person undertaking the reference tests.  |
| • 'Unclear' if insufficient information was provided.                    | • 'Unclear' if insufficient information was provided.                                                                    |
| Were uninterpretable results reported?                                  | • 'Yes' if the paper stated whether there were any uninterpretable or invalid results, and how those were handled; for example whether they were repeated until a valid result was obtained, or excluded from the analysis.  |
| • 'No' if the number of participants presented in the analysis did not match the number of participants originally enrolled in the study, and insufficient explanation was provided for any discrepancy.  |
| Were any withdrawals explained?                                         | • 'Unclear' if uninterpretable or invalid test results were not mentioned, but the number of participants presented in the analysis corresponded to the number of participants reported to be originally recruited into the study, or if insufficient information was given to permit this judgement; for example if the original number of participants recruited into the study was unclear.  |
| • 'Yes' if it was clear that no participants were excluded from the analysis (the number participants originally enrolled was clearly stated, and corresponded to the number presented in the analysis) or if exclusions were adequately described.  |
| Were any withdrawals explained?                                         | • 'No' if there were participants missing or excluded from the analysis and there was no explanation given; usually where the number of participants reported to have been enrolled and the number presented in the analysis did not correspond.  |
| • 'Unclear' if not enough information was given to assess whether any participants were excluded from the analysis; for example if the original number of participants recruited into the study was unclear.  |
| We reported how many results were uninterpretable (of the total) and how these were handled in the analysis.  | We reported how many results were uninterpretable (of the total) and how these were handled in the analysis.  |
## Appendix 4. Direct comparisons between test types

| Study               | Sensitivity (true positives/malaria cases) (%) | Difference (95% CI) (%) | P value | Specificity (true negatives/non-cases) (%) | Difference (95% CI) (%) | P value |
|---------------------|-----------------------------------------------|-------------------------|---------|-------------------------------------------|-------------------------|---------|
|                     | Type 2                                        | Type 3                  | Type 2  | Type 3                                    |                         |         |
| Ashton 2010         | 85 (209/246)                                 | 85 (209/246)            | 0 (-6.3 to 6.3) | P = 1.00 | 96 (2052/2137) | 96 (2060/2137) | 0 (-1.5 to 0.8) | P = 0.58 |
| Eibach 2013         | 80 (4/5)                                     | 60 (3/5)                | 20.0 (-35.4 to 75.4) | P = 1.00 | 99 (716/722) | 99 (718/722) | 0 (-1.1 to 0.6) | P = 0.75 |
| Singh 2010          | 68 (39/57)                                   | 77 (44/57)              | -8.8 (-25.0 to 7.5) | P = 0.40 | 98 (308/315) | 98 (309/315) | 0 (-2.5 to 1.9) | P = 1.00 |
| van den Broek 2006  | 75 (217/291)                                 | 88 (256/292)            | -13.1 (-19.4 to -6.8) | P < 0.001 | 100 (604/605) | 99 (598/604) | 0.8 (0 to 1.7) | P = 0.07 |
| Dev 2004            | 71 (5/7)                                     | 90 (26/29)              | -18.2 (-53.5 to 17.0) | P = 0.24 | 100 (23/23) | 100 (111) | (111/estimable) | Not estimable |
| Ratsimbasaoa 2007   | 73 (11/15)                                   | 80 (12/15)              | -6.7 (-36.8 to 23.5) | P = 1.0 | 98 (175/179) | 97 (175/180) | 0.50 (-2.7 to 3.8) | P = 1.0 |

We presented the difference in sensitivities and specificities between test types compared within each study as percentages. If a study evaluated more than one commercial brand of a test type on the same patients against the same reference standard, we randomly selected one brand for the comparison of test types.
Appendix 5. Comparison of microscopy and PCR reference standards for non-falciparum infections

| Test type, RDT brand | Microscopy | PCR |
|----------------------|------------|-----|
|                      | Number of studies | Number of participants | Sensitivity (95% CI) (%) | Specificity (95% CI) (%) | Number of studies | Number of participants | Sensitivity (95% CI) (%) | Specificity (95% CI) (%) |
| Type 3, CareStart Pf/Pan | 4 | 3544 | 74 (45 to 91) | 99 (96 to 100) | 179 | 91 (81 to 97) | 100 (97 to 100) |
| Type 3, Parascreen | 14 | 5407 | 79 (67 to 88) | 98 (98 to 99) | 659 | 84 (70 to 92) | 99 (97 to 100) |
| Type 3, One Step Malaria Pf/Pan | 1 | 606 | 70 (58 to 81) | 99 (98 to 100) | 606 | 72 (60 to 82) | 97 (95 to 98) |
| Type 3, SD Malaria Antigen Bioline | 4 | 3769 | 80 (73 to 85) | 99 (98 to 100) | 196 | 64 (41 to 83) | 99 (97 to 100) |
| Type 4, OptiMAL | 6 | 1843 | 90 (85 to 93) | 98 (97 to 99) | 313 | 88 (64 to 99) | 98 (96 to 99) |

**Contributions of Authors**

The review authors jointly developed the protocol. Katharine Abba applied inclusion criteria, oversaw the data extraction and entered the data. Yemisi Takwoingi, Sarah Donegan, Amanda Kirkham and Jon Deeks performed statistical analyses. All review authors contributed to the final manuscript.

**Declaration of Interest**

PG is Director of Evidence Building and Synthesis Research Consortium that receives money to increase the number of evidence-informed decisions by intermediary organizations, including WHO and national decision-makers that benefit the poor in middle- and low-income countries. PG is the coordinator of a WHO Collaborating Centre for Evidence Synthesis for Infectious and Tropical Diseases; one of the Centre's aims is to help WHO in its role as an infomediary in communicating reliable summaries of research evidence to policy makers, clinicians, teachers, and the public in developing countries.
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**DIFFERENCES BETWEEN PROTOCOL AND REVIEW**

In the protocol, we considered RDTs for the detection of *P. falciparum* and non-falciparum malaria within one Cochrane Review. However, it became apparent during production of the review that such a publication would be very large. For this reason we decided to split results for the different target conditions into two separate Cochrane Reviews.

In the protocol, we stated that in the search for eligible studies we would contact test manufacturers to identify any unpublished studies, handsearch conference proceedings and contact study authors and other experts for information on ongoing and unpublished studies. However, due to the number of citations returned by our search (over 4000) and the large size of the reviews, we did not have the resources to undertake any of these additional search methods, and the methods stated in the review reflect this.

Since the publication of the protocol, we added three additional exclusion criteria relating to study eligibility. We excluded studies if the study authors used active case detection to recruit participants, as we felt the threshold of symptoms leading to testing may be lower than for a self-selecting sample attending healthcare facilities and that this may influence the findings. We also excluded studies if they did not present sufficient data to allow us to extract or calculate absolute numbers of true positives, false positives, false negatives and true negatives, as we considered it would be distracting to the reader to present data on studies that did not contribute to the analyses. Due to resource constraints, we excluded studies if they were written in non-English languages, or if they did not provide enough information to enable a full assessment of their eligibility for the review.