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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.
Cochrane Database of Systematic Reviews 2014, Issue 12. Art. No.: CD011431.
DOI: 10.1002/14651858.CD011431.

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[Diagnostic Test Accuracy Review]

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

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Editorial group: Cochrane Infectious Diseases Group.
Publication status and date: Unchanged, published in Issue 4, 2015.

Citation: Abba K, Kirkham AJ, Olliaro PL, Deeks JJ, Donegan S, Garner P, Takwoingi Y. Rapid diagnostic tests for diagnosing uncomplicated non-falciparum or *Plasmodium vivax* malaria in endemic countries. *Cochrane Database of Systematic Reviews* 2014, Issue 12. Art. No.: CD011431. DOI: 10.1002/14651858.CD011431.

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.

RDTs 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 P.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.

12 April 2019

No update planned

Review superseded

This Cochrane Review has been superseded by Choi 2019 https://doi.org/10.1002/14651858.CD013218

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 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.

SUMMARY OF FINDINGS

Summary of findings 1. Performance of RDTs for diagnosis of non-falciparum or *P. vivax* malaria

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

Test type	**Quantity of evidence** **Number of evaluations (malaria cases/participants)**	**Average sensitivity (95% CI)**	**Average specificity (95% CI)**	**Prevalence (%)**	**Consequences in a cohort of 1000**	
					Missed cases	**False positives**
Target condition (reference standard): non-falciparum malaria (microscopy)						
Type 2 HRP-2 (*P. falciparum* specific) and aldolase (pan-specific)	11 (958/6879)	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	10 (986/3831)	89% (79% to 95%)	98% (97% to 99%)	5	6	19

pLDH (*P. falciparum* specific) and pLDH (pan-specific)				15	17	17
				30	33	14
Target condition (reference standard): non-falciparum malaria (PCR)						
Type 3	5 (300/1639)	81% (72% to 88%)	99% (97% to 99%)	5	10	10
HRP-2 (*P. falciparum* specific) and pLDH (pan-specific)				15	29	9
				30	57	7
Target condition (reference standard): P.*vivax* with or without other malaria species (microscopy)						
HRP-2 (*P. falciparum* specific) and pLDH (*P. vivax*-specific)	8 (580/3682)	95% (86% to 99%)	99% (99% to 100%)	5	3	10
				15	8	9
				30	15	7

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.

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 gametocytaemia (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 antigenaemia', 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, Immumochromatography, 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 excluded 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. Similiarly, 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.

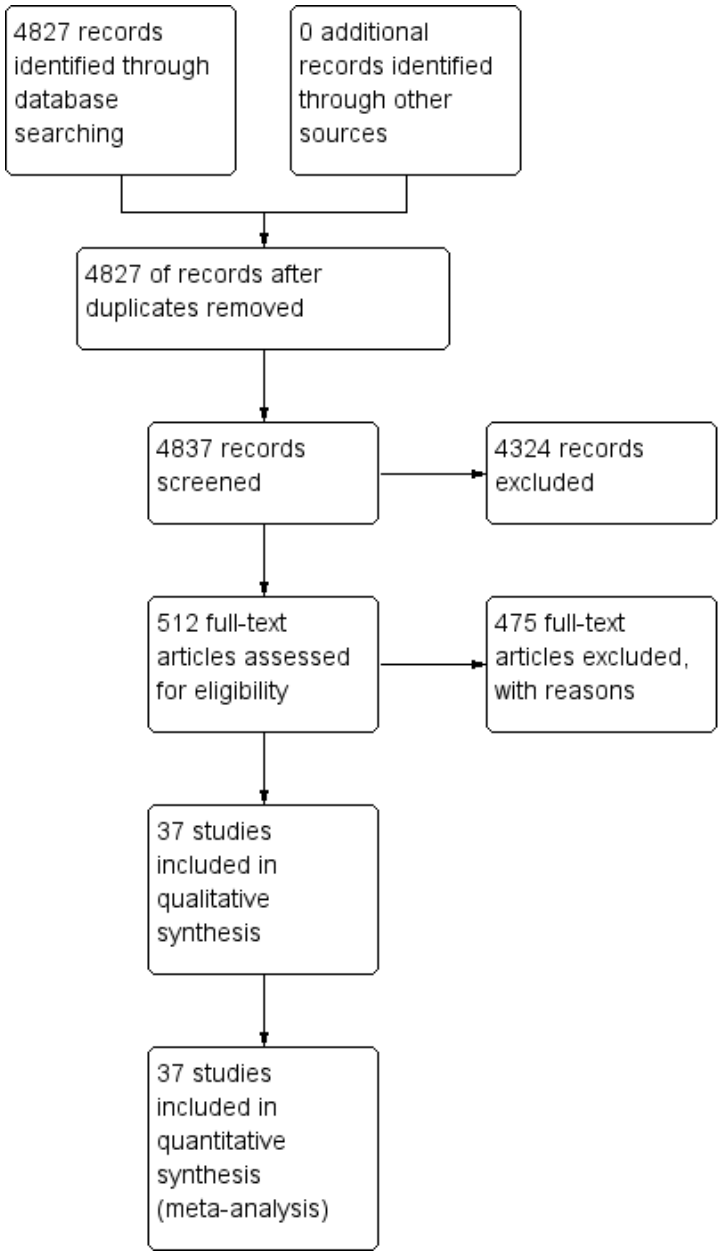
We did not attempt to assess reporting bias because little is known about how this should be done for diagnostic test accuracy (DTA) reviews.

RESULTS

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 *P. 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.

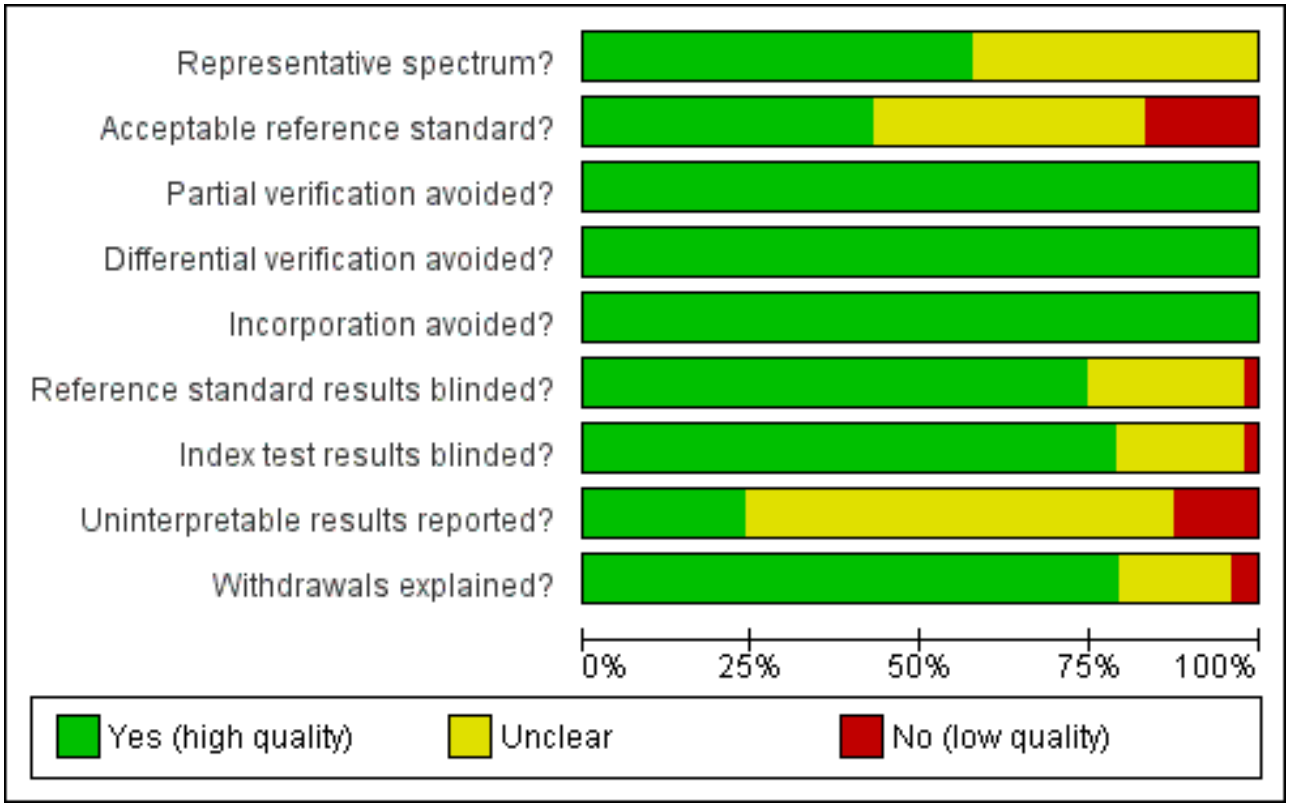


We therefore included a total of 37 study publications. One of the included publications described two related studies, and another publication reported data separately for 10 different sites, making a total of 47 study cohorts. Seven of the 47 cohorts evaluated more than one test; one compared four 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.

Figure 2. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies.



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 enrolled 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.

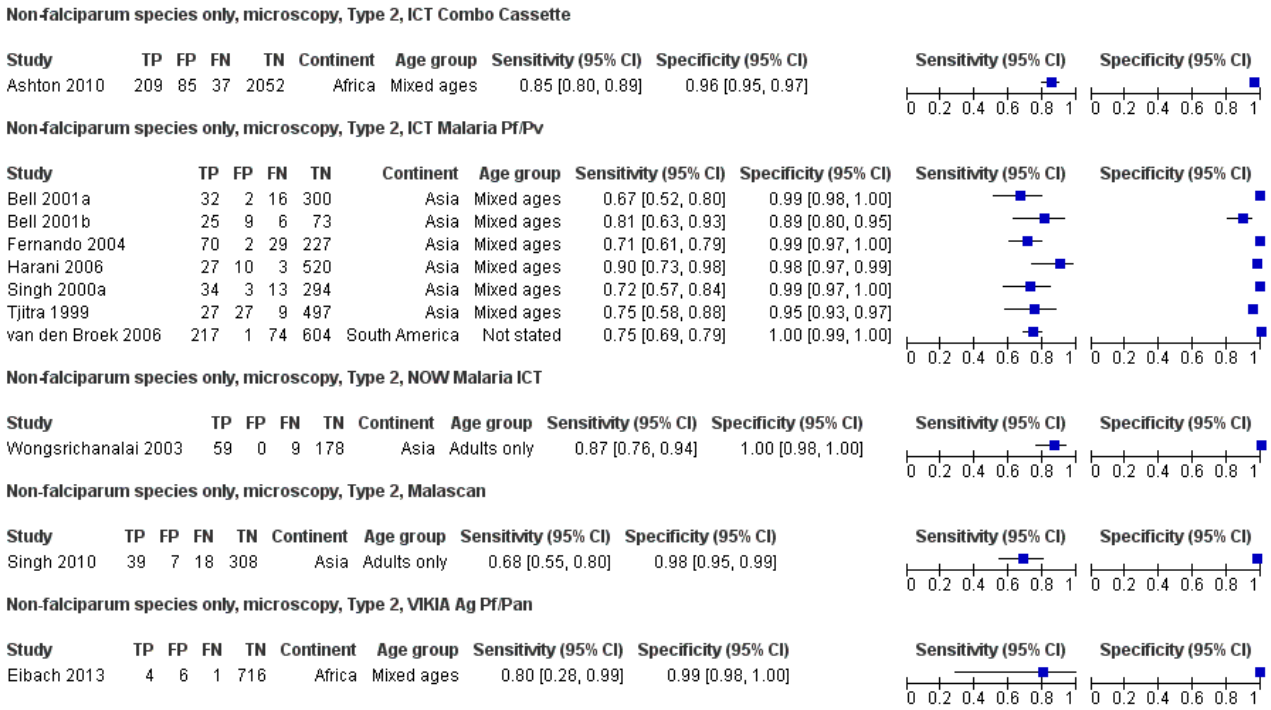
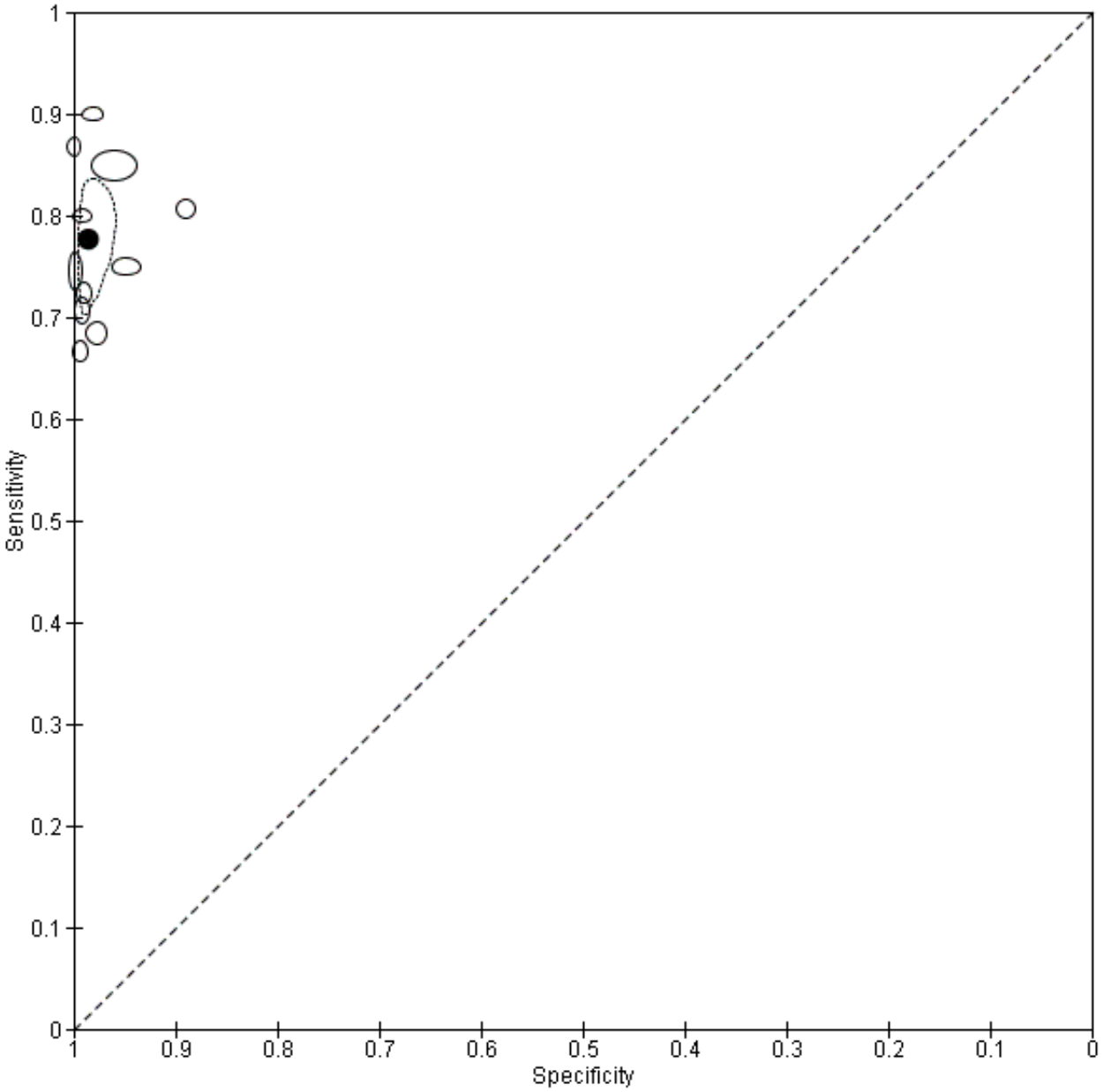


Figure 4. Summary ROC plot of Type 2 tests for detection of non-falciparum species (verified with microscopy). The black solid circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.



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.

Non-falciparum species only, microscopy, Type 3, Parascreen

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ashton 2010	203	96	43	2041	Africa	Mixed ages	0.83 [0.77, 0.87]	0.96 [0.95, 0.96]
Endeshaw 2012a	3	4	3	190	Africa	Mixed ages	0.50 [0.12, 0.88]	0.98 [0.95, 0.99]
Endeshaw 2012b	32	4	4	160	Africa	Mixed ages	0.89 [0.74, 0.97]	0.98 [0.94, 0.99]
Endeshaw 2012c	6	3	5	184	Africa	Mixed ages	0.55 [0.23, 0.83]	0.98 [0.95, 1.00]
Endeshaw 2012d	2	1	2	195	Africa	Mixed ages	0.50 [0.07, 0.93]	0.99 [0.97, 1.00]
Endeshaw 2012e	5	7	0	185	Africa	Mixed ages	1.00 [0.48, 1.00]	0.96 [0.93, 0.99]
Endeshaw 2012f	8	0	0	192	Africa	Mixed ages	1.00 [0.63, 1.00]	1.00 [0.98, 1.00]
Endeshaw 2012g	3	1	2	192	Africa	Mixed ages	0.60 [0.15, 0.95]	0.99 [0.97, 1.00]
Endeshaw 2012h	14	0	2	184	Africa	Mixed ages	0.88 [0.62, 0.98]	1.00 [0.98, 1.00]
Endeshaw 2012i	10	4	0	186	Africa	Mixed ages	1.00 [0.69, 1.00]	0.98 [0.95, 0.99]
Endeshaw 2012j	4	3	12	181	Africa	Mixed ages	0.25 [0.07, 0.52]	0.98 [0.95, 1.00]
Singh 2010	44	6	13	309	Asia	Adults only	0.77 [0.64, 0.87]	0.98 [0.96, 0.99]
Elahi 2013	49	3	5	270	Asia	Mixed ages	0.91 [0.80, 0.97]	0.99 [0.97, 1.00]
Bendezu 2010	64	6	19	243	South America	Adults only	0.77 [0.67, 0.86]	0.98 [0.95, 0.99]

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

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ashton 2010	209	77	37	2060	Africa	Mixed ages	0.85 [0.80, 0.89]	0.96 [0.96, 0.97]
Eibach 2013	3	4	2	718	Africa	Mixed ages	0.60 [0.15, 0.95]	0.99 [0.99, 1.00]
Moges 2012	20	4	38	192	Africa	Mixed ages	0.34 [0.22, 0.48]	0.98 [0.95, 0.99]
Xiaodong 2013	59	0	6	115	Asia	Mixed ages	0.91 [0.81, 0.97]	1.00 [0.97, 1.00]

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

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ratsimbasoa 2007	11	4	4	175	Africa	Mixed ages	0.73 [0.45, 0.92]	0.98 [0.94, 0.99]
Dev 2004	5	0	2	23	Asia	Mixed ages	0.71 [0.29, 0.96]	1.00 [0.85, 1.00]
Kosack 2013	454	26	133	1972	Asia	Mixed ages	0.77 [0.74, 0.81]	0.99 [0.98, 0.99]
Trouvay 2013	111	3	18	828	South America	Mixed ages	0.86 [0.79, 0.92]	1.00 [0.99, 1.00]

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

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Singh 2010	48	11	9	304	Asia	Adults only	0.84 [0.72, 0.93]	0.97 [0.94, 0.98]
Bharti 2008	34	15	7	235	Asia	Mixed ages	0.83 [0.68, 0.93]	0.94 [0.90, 0.97]

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

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Yan 2013	51	5	22	528	Asia	Mixed ages	0.70 [0.58, 0.80]	0.99 [0.98, 1.00]

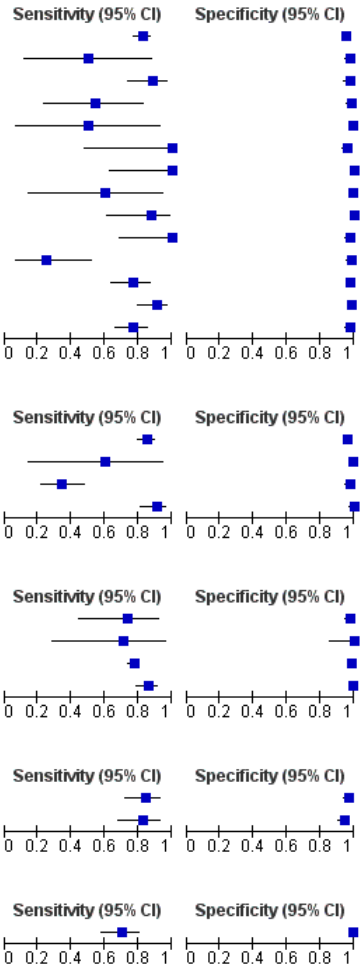
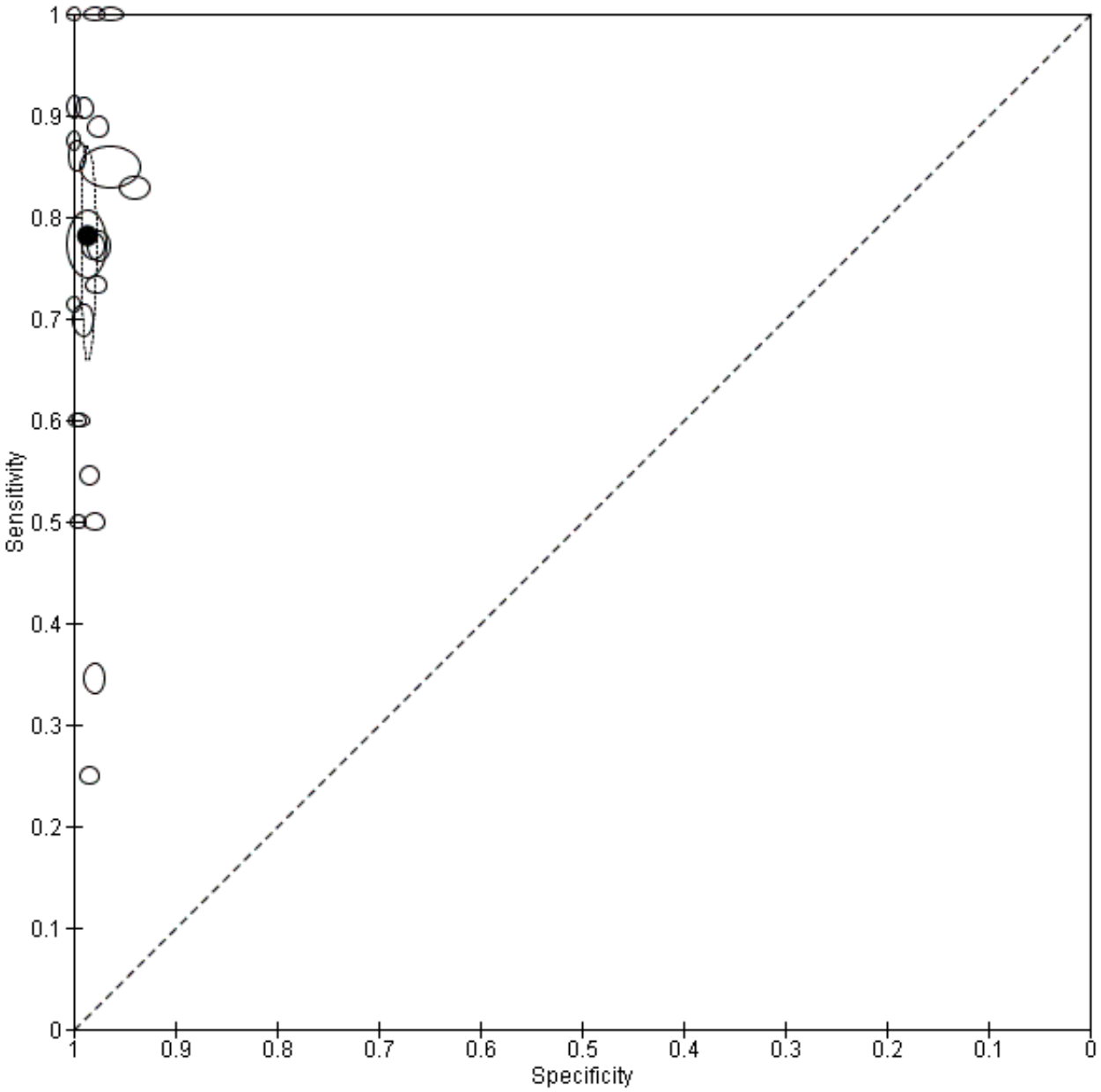


Figure 6. Summary ROC plot of Type 3 tests for detection of non-falciparum species (verified with microscopy). The black solid circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.



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.

Non-falciparum species only, microscopy, Type 4, OptiMAL

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ratsimbasoa 2007	15	2	2	175	Africa	Mixed ages	0.88 [0.64, 0.99]	0.99 [0.96, 1.00]
Dev 2004	26	0	3	111	Asia	Mixed ages	0.90 [0.73, 0.98]	1.00 [0.97, 1.00]
Singh 2003	22	1	0	57	Asia	Mixed ages	1.00 [0.85, 1.00]	0.98 [0.91, 1.00]
Valecha 2003	173	16	13	497	Asia	Mixed ages	0.93 [0.88, 0.96]	0.97 [0.95, 0.98]
Chayani 2004	23	2	3	204	Asia	Not stated	0.88 [0.70, 0.98]	0.99 [0.97, 1.00]
Kolaczinski 2004	142	5	23	328	Asia	Not stated	0.86 [0.80, 0.91]	0.98 [0.97, 1.00]

Non-falciparum species only, microscopy, Type 4, OptiMAL-IT

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Pattanasin 2003	56	2	29	179	Asia	Mixed ages	0.66 [0.55, 0.76]	0.99 [0.96, 1.00]
Andrade 2010	84	14	0	213	South America	Mixed ages	1.00 [0.96, 1.00]	0.94 [0.90, 0.97]
Metzger 2011	52	6	30	426	South America	Not stated	0.63 [0.52, 0.74]	0.99 [0.97, 0.99]
van den Broek 2006	256	6	36	598	South America	Not stated	0.88 [0.83, 0.91]	0.99 [0.98, 1.00]

Non-falciparum species only, microscopy, Type 4, Carestart

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ratsimbasoa 2007	12	5	3	175	Africa	Mixed ages	0.80 [0.52, 0.96]	0.97 [0.94, 0.99]

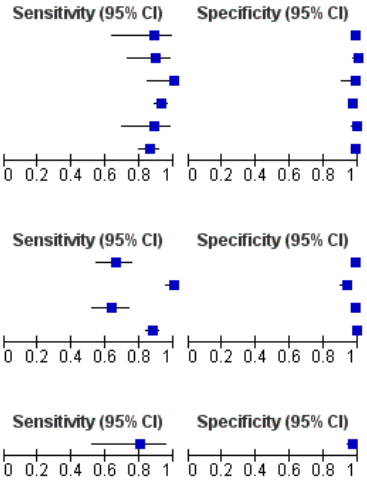
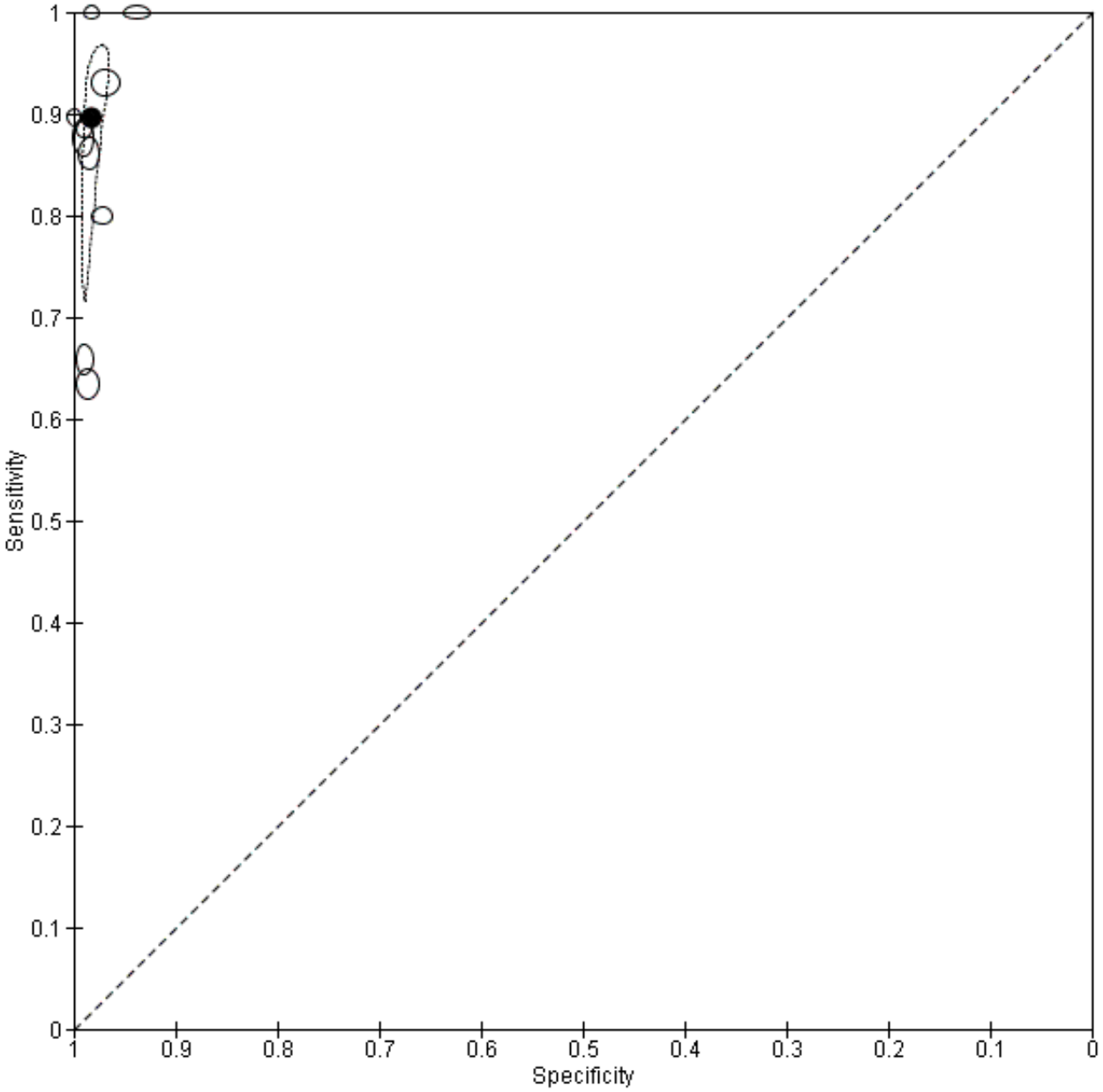


Figure 8. Summary ROC plot of Type 4 tests for detection of non-falciparum species (verified with microscopy). The black circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.



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

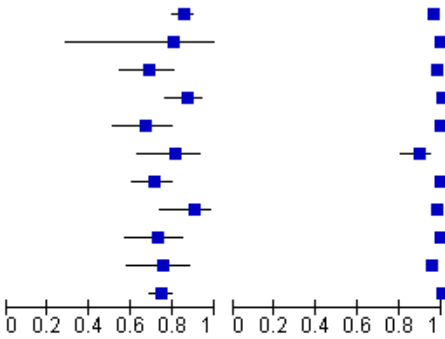
We summarised the comparison of different RDT types in Figure 9, Figure 10, Table 5 and Table 6. There was a statistically significant (P = 0.008) difference in accuracy between test types (Table 5) with Type 4 tests being significantly more sensitive than Type 2 (P = 0.01) and Type 3 (P = 0.03) (Table 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.

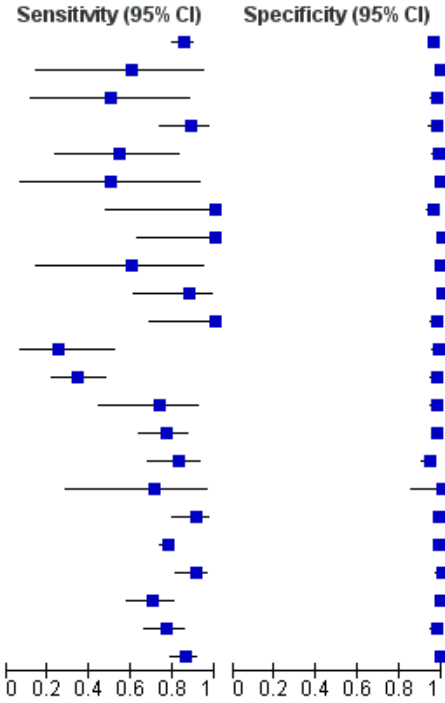
Non-falciparum species only, microscopy, Type 2 (All)

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ashton 2010	209	85	37	2052	Africa	Mixed ages	0.85 [0.80, 0.89]	0.96 [0.95, 0.97]
Eibach 2013	4	6	1	716	Africa	Mixed ages	0.80 [0.28, 0.99]	0.99 [0.98, 1.00]
Singh 2010	39	7	18	308	Asia	Adults only	0.68 [0.55, 0.80]	0.98 [0.95, 0.99]
Wongsrichanalai 2003	59	0	9	178	Asia	Adults only	0.87 [0.76, 0.94]	1.00 [0.98, 1.00]
Bell 2001a	32	2	16	300	Asia	Mixed ages	0.67 [0.52, 0.80]	0.99 [0.98, 1.00]
Bell 2001b	25	9	6	73	Asia	Mixed ages	0.81 [0.63, 0.93]	0.89 [0.80, 0.95]
Fernando 2004	70	2	29	227	Asia	Mixed ages	0.71 [0.61, 0.79]	0.99 [0.97, 1.00]
Harani 2006	27	10	3	520	Asia	Mixed ages	0.90 [0.73, 0.98]	0.98 [0.97, 0.99]
Singh 2000a	34	3	13	294	Asia	Mixed ages	0.72 [0.57, 0.84]	0.99 [0.97, 1.00]
Tjitra 1999	27	27	9	497	Asia	Mixed ages	0.75 [0.58, 0.88]	0.95 [0.93, 0.97]
van den Broek 2006	217	1	74	604	South America	Not stated	0.75 [0.69, 0.79]	1.00 [0.99, 1.00]



Non-falciparum species only, microscopy, Type 3 (All)

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ashton 2010	209	77	37	2060	Africa	Mixed ages	0.85 [0.80, 0.89]	0.96 [0.96, 0.97]
Eibach 2013	3	4	2	718	Africa	Mixed ages	0.60 [0.15, 0.95]	0.99 [0.99, 1.00]
Endeshaw 2012a	3	4	3	190	Africa	Mixed ages	0.50 [0.12, 0.88]	0.98 [0.95, 0.99]
Endeshaw 2012b	32	4	4	160	Africa	Mixed ages	0.89 [0.74, 0.97]	0.98 [0.94, 0.99]
Endeshaw 2012c	6	3	5	184	Africa	Mixed ages	0.55 [0.23, 0.83]	0.98 [0.95, 1.00]
Endeshaw 2012d	2	1	2	195	Africa	Mixed ages	0.50 [0.07, 0.93]	0.99 [0.97, 1.00]
Endeshaw 2012e	5	7	0	185	Africa	Mixed ages	1.00 [0.48, 1.00]	0.96 [0.93, 0.99]
Endeshaw 2012f	8	0	0	192	Africa	Mixed ages	1.00 [0.63, 1.00]	1.00 [0.98, 1.00]
Endeshaw 2012g	3	1	2	192	Africa	Mixed ages	0.60 [0.15, 0.95]	0.99 [0.97, 1.00]
Endeshaw 2012h	14	0	2	184	Africa	Mixed ages	0.88 [0.62, 0.98]	1.00 [0.98, 1.00]
Endeshaw 2012i	10	4	0	186	Africa	Mixed ages	1.00 [0.69, 1.00]	0.98 [0.95, 0.99]
Endeshaw 2012j	4	3	12	181	Africa	Mixed ages	0.25 [0.07, 0.52]	0.98 [0.95, 1.00]
Moges 2012	20	4	38	192	Africa	Mixed ages	0.34 [0.22, 0.48]	0.98 [0.95, 0.99]
Ratsimbasoa 2007	11	4	4	175	Africa	Mixed ages	0.73 [0.45, 0.92]	0.98 [0.94, 0.99]
Singh 2010	44	6	13	309	Asia	Adults only	0.77 [0.64, 0.87]	0.98 [0.96, 0.99]
Bharti 2008	34	15	7	235	Asia	Mixed ages	0.83 [0.68, 0.93]	0.94 [0.90, 0.97]
Dev 2004	5	0	2	23	Asia	Mixed ages	0.71 [0.29, 0.96]	1.00 [0.85, 1.00]
Elahi 2013	49	3	5	270	Asia	Mixed ages	0.91 [0.80, 0.97]	0.99 [0.97, 1.00]
Kosack 2013	454	26	133	1972	Asia	Mixed ages	0.77 [0.74, 0.81]	0.99 [0.98, 0.99]
Xiaodong 2013	59	0	6	115	Asia	Mixed ages	0.91 [0.81, 0.97]	1.00 [0.97, 1.00]
Yan 2013	51	5	22	528	Asia	Mixed ages	0.70 [0.58, 0.80]	0.99 [0.98, 1.00]
Bendezu 2010	64	6	19	243	South America	Adults only	0.77 [0.67, 0.86]	0.98 [0.95, 0.99]
Trouvay 2013	111	3	18	828	South America	Mixed ages	0.86 [0.79, 0.92]	1.00 [0.99, 1.00]



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

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Ratsimbasoa 2007	12	5	3	175	Africa	Mixed ages	0.80 [0.52, 0.96]	0.97 [0.94, 0.99]
Dev 2004	26	0	3	111	Asia	Mixed ages	0.90 [0.73, 0.98]	1.00 [0.97, 1.00]
Pattanasin 2003	56	2	29	179	Asia	Mixed ages	0.66 [0.55, 0.76]	0.99 [0.96, 1.00]
Singh 2003	22	1	0	57	Asia	Mixed ages	1.00 [0.85, 1.00]	0.98 [0.91, 1.00]
Valecha 2003	173	16	13	497	Asia	Mixed ages	0.93 [0.88, 0.96]	0.97 [0.95, 0.98]
Chayani 2004	23	2	3	204	Asia	Not stated	0.88 [0.70, 0.98]	0.99 [0.97, 1.00]
Kolaczinski 2004	142	5	23	328	Asia	Not stated	0.86 [0.80, 0.91]	0.98 [0.97, 1.00]
Andrade 2010	84	14	0	213	South America	Mixed ages	1.00 [0.96, 1.00]	0.94 [0.90, 0.97]
Metzger 2011	52	6	30	426	South America	Not stated	0.63 [0.52, 0.74]	0.99 [0.97, 0.99]
van den Broek 2006	256	6	36	598	South America	Not stated	0.88 [0.83, 0.91]	0.99 [0.98, 1.00]

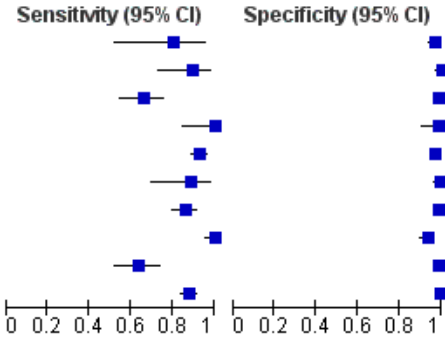
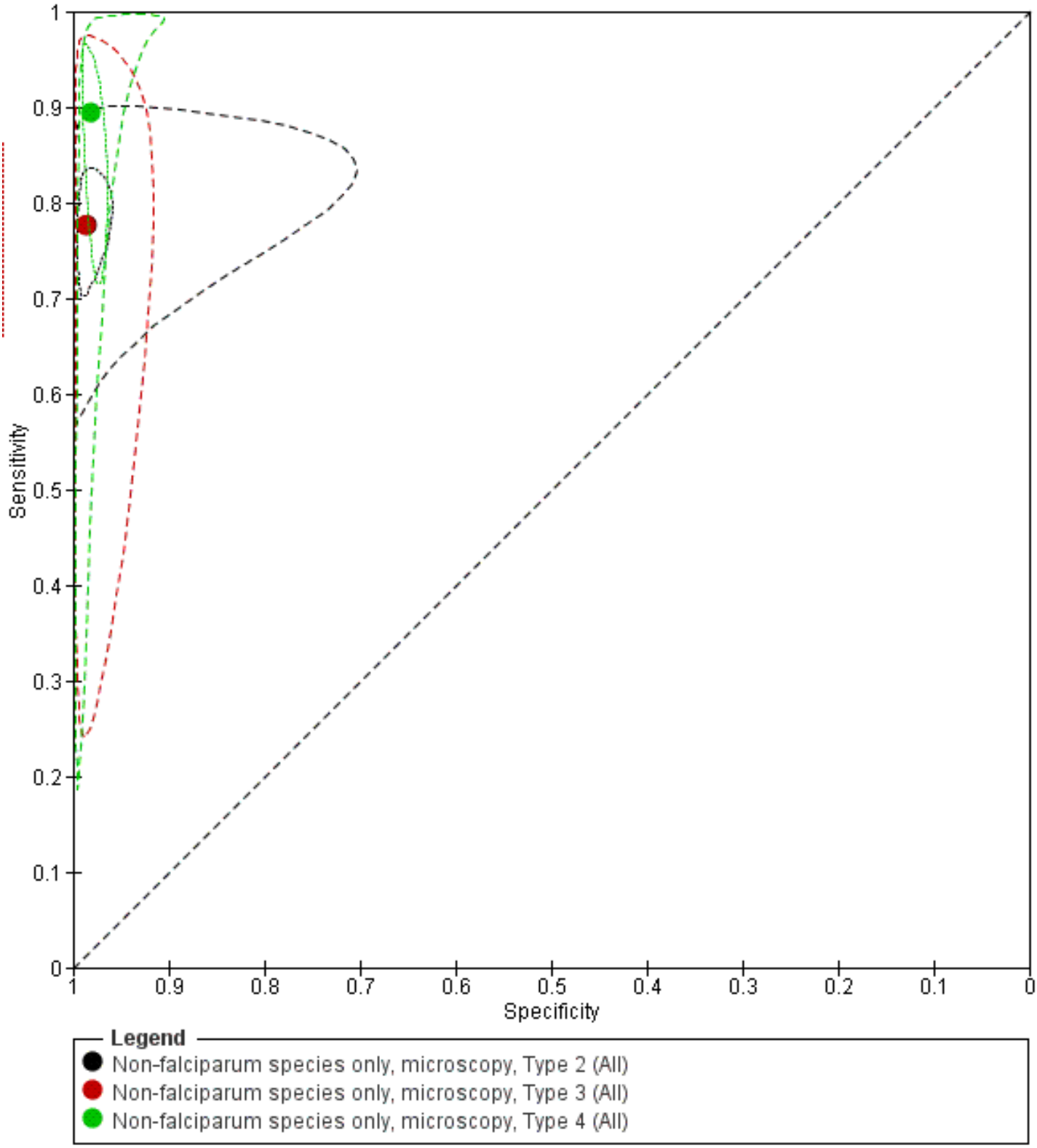


Figure 10. Summary ROC plot comparing Type 2, Type 3 and Type 4 tests for detection of non-falciparum species (verified with microscopy). The solid circles correspond to the summary estimates of sensitivity and specificity for each test type, and are shown with 95% confidence regions (dotted lines) and 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

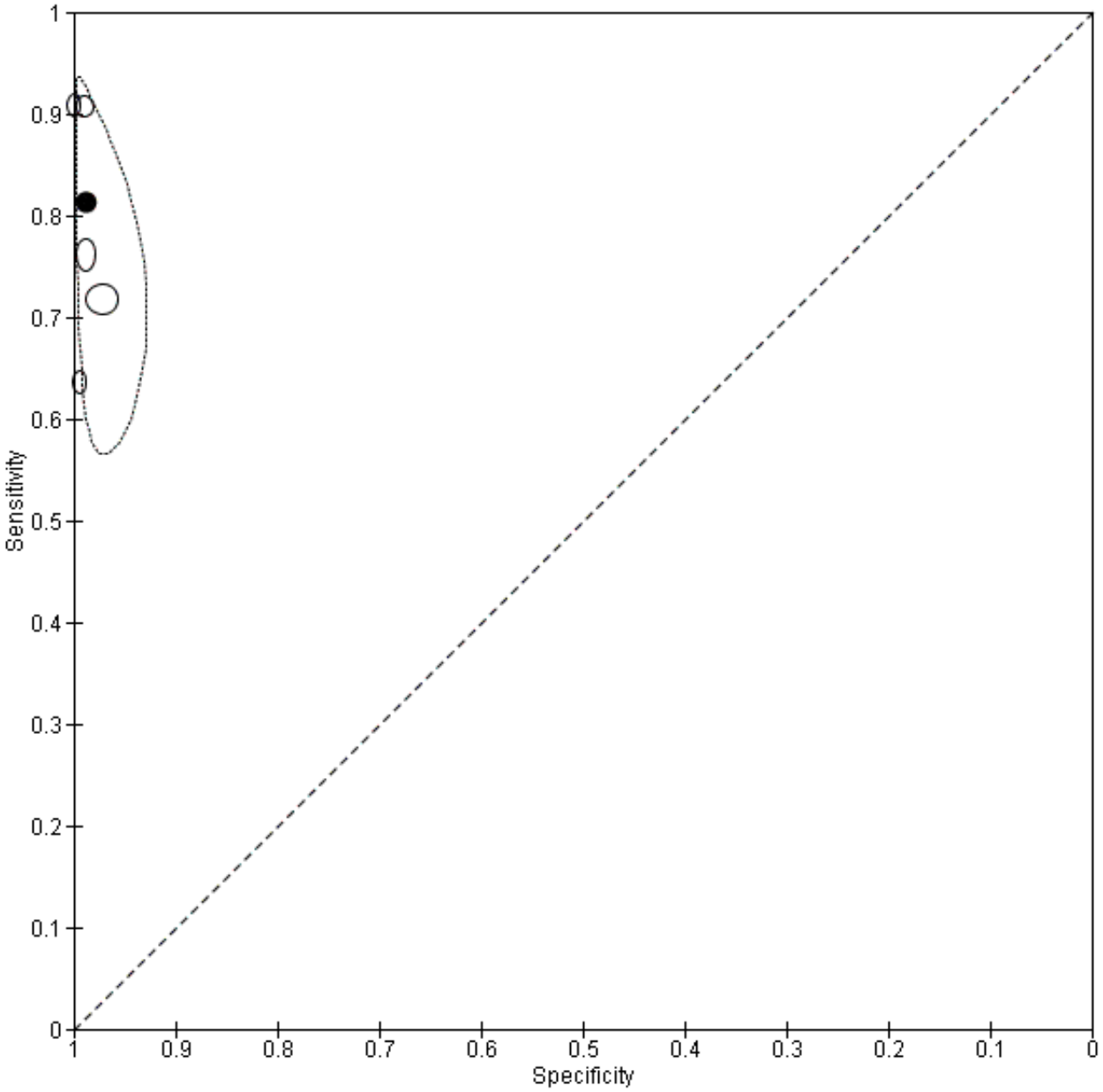
Type 2 tests

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 Xiaodong 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. Ratsimbasoa 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.

Study	TP	FP	FN	TN	Continent	Age group	Sensitivity (95% CI)	Specificity (95% CI)
Chanie 2011	25	4	0	1063	Africa	Mixed ages	1.00 [0.86, 1.00]	1.00 [0.99, 1.00]
Mekonnen 2010	61	0	3	176	Africa	Mixed ages	0.95 [0.87, 0.99]	1.00 [0.98, 1.00]
Sharew 2009	155	9	1	503	Africa	Mixed ages	0.99 [0.96, 1.00]	0.98 [0.97, 0.99]
Samane 2010	110	0	2	138	Africa	Not stated	0.98 [0.94, 1.00]	1.00 [0.97, 1.00]
Singh 2010	45	3	23	301	Asia	Adults only	0.66 [0.54, 0.77]	0.99 [0.97, 1.00]
Alam 2011	19	1	2	316	Asia	Mixed ages	0.90 [0.70, 0.99]	1.00 [0.98, 1.00]
Mohon 2012	71	4	2	295	Asia	Mixed ages	0.97 [0.90, 1.00]	0.99 [0.97, 1.00]
Yan 2013	45	5	16	284	Asia	Mixed ages	0.74 [0.61, 0.84]	0.98 [0.96, 0.99]

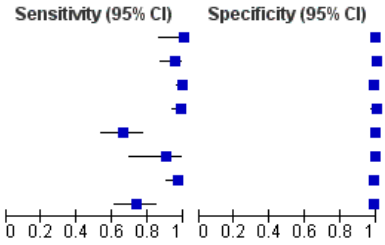
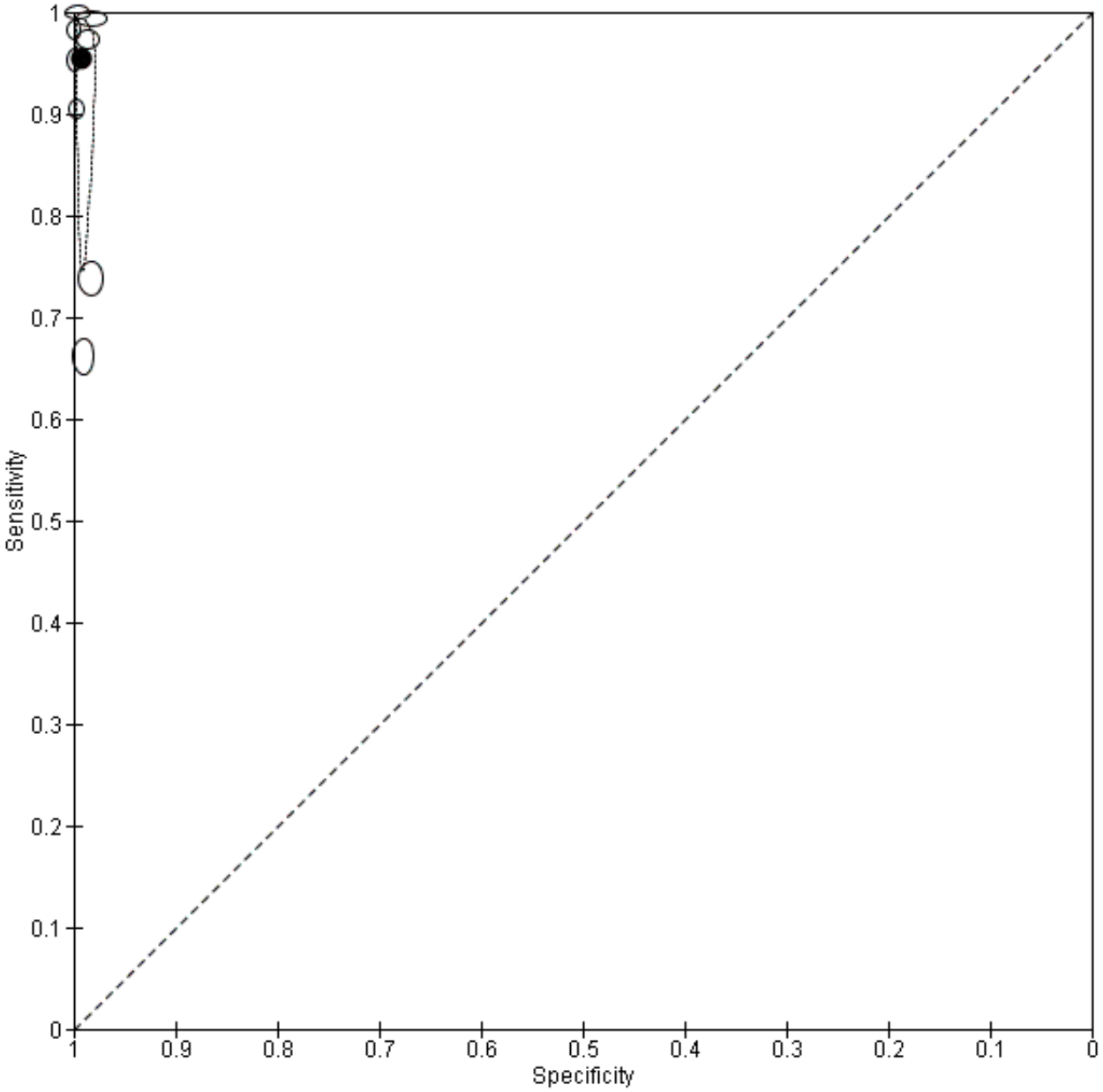


Figure 13. Summary ROC plot Pf HRP-2 and Pv pLDH for detection of *P. vivax* (verified with microscopy). The black circle corresponds to the summary estimate of sensitivity and specificity, and is shown with a 95% confidence region.



Verified by PCR

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 500 asexual parasites per µL to 100%. In Kosack 2013 sensitivity was 14% at one to nine 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.

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 1, 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

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.

ACKNOWLEDGEMENTS

The academic editor for this review was Dr Karen Steingart.

We are grateful to our affiliated institutions and organizations, and to the Department of International Development (DFID), UK for research grants. We acknowledge the referees for their comments. Also, we thank Nicola Mayan and Sally Jackson for helping with data extraction.

The editorial base for the Cochrane Infectious Diseases Group is funded by UKaid from the UK Government for the benefit of developing countries.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

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 (MarchMay) and post-monsoon (September to November) periods **Malaria endemic species:** *P. falciparum* and *P. vivax*
Participants	**Sample size:** 338

Alam 2011 *(Continued)*

	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

Alam 2011 *(Continued)*

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.
Withdrawals explained? All tests	Yes	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 **Previous 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

Andrade 2010 *(Continued)*

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.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	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? All tests	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? All tests	Yes	All participants who received the index test also received the reference tests.
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 standard.
Reference standard results blinded? All tests	Unclear	Not reported whether the tests were read blindly.
Index test results blinded?	Unclear	Not reported whether the tests were read blindly.

Andrade 2010 *(Continued)*
All tests

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.

Ashton 2010

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)

Ashton 2010 *(Continued)*

- 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".

Ashton 2010 *(Continued)*

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.

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 Maindano) **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	**Commerical 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

Bell 2001a *(Continued)*

	Transport and storage conditions: Refrigerated until 2 weeks before use **Person(s) performing RDT:** Researchers **RDT setting:** Study villages
Follow-up	Not applicable
Notes	**Source of funding:** The Australian National Health and Medical Research Council.

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants had approached village health workers with symptoms suggestive of malaria, but the sampling method was not described.
Acceptable reference standard? All tests	Yes	An experienced microscopist viewed at least 100 high powered fields and discordant results were re-examined.
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	"slides were read by a local microscopist who was not aware of the results of the ICT tests".
Index test results blinded? All tests	Yes	RDTs were performed 2 to 4 weeks before microscopy.
Uninterpretable results reported? All tests	Yes	The paper reported that there was 1 uninterpretable microscopy result.
Withdrawals explained? All tests	Unclear	The number of participants originally enrolled in the study was not stated; therefore it is unclear whether there were any withdrawals.

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 Maindano)

Bell 2001b *(Continued)*

	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 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?** 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	**Commerical 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
Representative spectrum? All tests	Unclear	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?	Unclear	No details given of the microscopy process.

Bell 2001b *(Continued)*

All tests		
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	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	Yes	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	Yes	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	Yes	Only 113 microscopy results could be matched with RDT results by name and date; the others were lost from the analysis.

Bendezu 2010

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

Bendezu 2010 *(Continued)*

	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? All tests	Yes	Participants were attending health centres with fever and no history of malaria treatment within the last 2 weeks.
Acceptable reference standard? All tests	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? 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 standard.
Reference standard results blinded? All tests	Yes	Reported that the tests were read blindly.
Index test results blinded? All tests	Yes	Reported that the tests were read blindly.

Bendezu 2010 *(Continued)*

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.

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	**Commerical 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

Bharti 2008 *(Continued)*

	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? All tests	Yes	Participants were a consecutive sample of people attending mobile field clinics with fever or history of fever, and suspicion of malaria.
Acceptable reference standard? All tests	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? 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 was undertaken "without reference to the RDT".
Index test results blinded? All tests	Yes	RDTs were undertaken on site, and the results recorded before the microscopy results became available.
Uninterpretable results reported? All tests	Yes	The paper reported that there were no invalid results.
Withdrawals explained? All tests	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

Chanie 2011 *(Continued)*

	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.

Chanie 2011 *(Continued)*

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.
Incorporation avoided? All tests	Yes	The reference standard was microscopy.
Reference standard results blinded? All tests	Unclear	Blinding procedures not stated. However, microscopic evaluation and RDT were performed independently. Results were recorded in separate sheets.
Index test results blinded? All tests	Unclear	Blinding procedures not stated. However, microscopic evaluation and RDT were performed independently. Results were recorded in separate sheets.
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 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

Chayani 2004 *(Continued)*

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.

Chayani 2004 *(Continued)*

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; therefore it is not possible to judge whether any were excluded from the analysis due to invalid test results.
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:**

Dev 2004 *(Continued)*

- Paracheck Pf (Orchid Biomedical Systems, Goa, India)
- ParaSight-F (Beckton Dickinson, Franklin Lakes, NJ)
- ParaHIT-F (Span diagnostics Ltd, Surat, India)
- ICT Malaria Pf (ICT Diagnostics, Sydney, Australia)
- New Pf-1 mini (Monozyme India Ltd, Secundrabad, India)
- SD Malaria Pf/Pv (SD Diagnostics Inc, Korea)
- Diamed OptiMAL (Flow Inc. Portlad, OR)

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? All tests	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? All tests	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.

Dev 2004 *(Continued)*

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.

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

Eibach 2013 *(Continued)*

	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? All tests	Yes	Consecutive sample of people attending a clinic with symptoms of malaria.
Acceptable reference standard? All tests	Yes	Microscopy was undertaken by 2 trained local health workers and corrected by PCR at the Parasitology Department of the Lyon University Hospital.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference tests.
Differential verification avoided? All tests	Yes	The same reference test was used.

Eibach 2013 *(Continued)*

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

Elahi 2013 *(Continued)*

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? All tests	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? All tests	Unclear	Microscopy was undertaken by 2 experienced microscopists, but the number of fields viewed before declaring a slide negative was not stated. PCR was also used as a separate, additional reference standard.
Partial verification avoided? All tests	Yes	All participants received both the reference test and the index 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 the reference standard.
Reference standard results blinded? All tests	Yes	Microscopists were blinded to prior results.
Index test results blinded? All tests	Unclear	Blinding not described, however, index and reference tests were undertaken at different locations.
Uninterpretable results reported? All tests	No	Uninterpretable results were not reported on.
Withdrawals explained? All tests	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.

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
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."

Endeshaw 2012a *(Continued)*

"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 field 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 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 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)

Endeshaw 2012b *(Continued)*

	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.

Endeshaw 2012b *(Continued)*

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.

Endeshaw 2012c

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

Endeshaw 2012c *(Continued)*

	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 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.

Endeshaw 2012c *(Continued)*

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 2012d

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

Endeshaw 2012d *(Continued)*

	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, the 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 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 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

Endeshaw 2012e *(Continued)*

	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

Endeshaw 2012e *(Continued)*

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 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

Endeshaw 2012f *(Continued)*

	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 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?	Yes	The same reference test was used regardless of the index test results.

Endeshaw 2012f *(Continued)*

All tests		
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 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

Endeshaw 2012g *(Continued)*

	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
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.

Endeshaw 2012g *(Continued)*

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 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

Endeshaw 2012h *(Continued)*

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 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 2012i

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

Endeshaw 2012i *(Continued)*

	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.

Endeshaw 2012i *(Continued)*

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 2012j

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.

Endeshaw 2012j *(Continued)*

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 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?	Yes	Microscopy was used as reference standard.

Endeshaw 2012j *(Continued)*

All tests		
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.

Fernando 2004

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

Fernando 2004 *(Continued)*

Index and comparator tests	**Commerical 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.
Acceptable reference standard? All tests	Yes	2 independent trained microscopists viewed 400 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	Blinding not described.
Index test results blinded? All tests	Unclear	Blinding not described.
Uninterpretable results reported? All tests	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? 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.

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 eligibles. 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	**Commerical 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	

Harani 2006 *(Continued)*

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".
Index test results blinded? All tests	Yes	"These results were read by the second author who was blind to the microscopy results".
Uninterpretable results reported? All tests	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? All tests	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

Kolaczinski 2004 *(Continued)*

	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	**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:** 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? All tests	Yes	Participants were a consecutive series of patients attending a basic health units with suspected malaria.
Acceptable reference standard? All tests	Yes	2 microscopists, 1 working in a central laboratory, viewed at least 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	No	The index test and reference test were undertaken by the same person.

Kolaczinski 2004 *(Continued)*

Index test results blinded? All tests	No	The index test and reference test were undertaken by the same person.
Uninterpretable results reported? All tests	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? All tests	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 P.f/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

Kosack 2013 *(Continued)*

	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, presumable the RDTs were performed at the clinics.
Follow-up	Not applicable
Notes	**Source of funding:** Source of funding not reported

Table of Methodological Quality

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

Mekonnen 2010 *(Continued)*

	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	**Commerical 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:** Recieved financial support from the School of Laboratory Studies of the Jimma Univeristy and the VLIR-IUC program between Flanders and Jimma Univeristy. Access Bio Ltd donated the CareStart Malaria Pf/Pv Combo test kit

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants were attending a clinic with fever and suspected malaria, but the sampling method was not described.
Acceptable reference standard? All tests	Yes	Experienced technicians independently viewed 300 high power fields before declaring a slide negative. Discordant results was repeated independently.

Mekonnen 2010 *(Continued)*

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	Blinding not described.
Index test results blinded? All tests	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? All tests	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? All tests	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.

Metzger 2011

Clinical features and settings	**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*
Participants	**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
Study design	No details of the enrolment and sampling method were reported. 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?** Slides were examined by microscopists in health posts, then all positive and 10% of negative slides were re-examined by microscopists at the Re-

Metzger 2011 *(Continued)*

	gional 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
Index and comparator tests	**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 26.9C, 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.
Follow-up	Not applicable
Notes	**Source of funding:** UNICEF

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	No details of the characteristics of the participants were reported.
Acceptable reference standard? All tests	Yes	3 microscopists read the slides at either 200 fields or the complete smear before declaring a test as negative.
Partial verification avoided? All tests	Yes	"550 RDTs (OptiMAL-IT) ans concomitant slides originating from the HPs of Atures municipality were received in the order of their arrival at the RCL in Puerto Ayacucho".
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 standard.
Reference standard results blinded? All tests	Yes	Reported blinding.
Index test results blinded?	Yes	Reported blinding.

Metzger 2011 *(Continued)*
All tests

Uninterpretable results reported? All tests	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? All tests	Yes	"36 tests had to be excluded because coding was lost during transport and/or because they could not be clearly allocated".

Moges 2012

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 endemicity:** High endemicity **Malaria endemic species:** *P. vivax* and *P. falciparum*
Participants	**Sample size:** 254 **Age:** Mean 21.4 (SD14.76), range 0.4 to 75 years **Sex:** 61% male, 39% female **Co-morbidities or pregnancy:** Co-morbities 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

Moges 2012 *(Continued)*

	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

Table of Methodological Quality

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

Mohon 2012 *(Continued)*

	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? All tests	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? All tests	Yes	Microscopy was verified with PCR.
Partial verification avoided? All tests	Yes	All participants that received the index test had their diagnosis verified by reference test.

Mohon 2012 *(Continued)*

Differential verification avoided? All tests	Yes	PCR adjusted microscopy was used as the reference test.
Incorporation avoided? All tests	Yes	PCR adjusted microscopy was used as the reference test.
Reference standard results blinded? All tests	Unclear	Blinding not reported.
Index test results blinded? All tests	Unclear	Blinding not reported.
Uninterpretable results reported? All tests	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? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any withdrawals.

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

Pattanasin 2003 *(Continued)*

	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	**Commerical 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

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	All participants had a fever and suspected malaria, but the exact clinical setting and the sampling method were not described.
Acceptable reference standard? All tests	Unclear	No details of the microscopy process were given.
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?	Yes	Test results were recorded without reference to the microscopy results.

Pattanasin 2003 *(Continued)*
All tests

Uninterpretable results reported? All tests	Yes	Doubtful and invalid results were reported (5 of 271).
Withdrawals explained? All tests	Unclear	Almost all participants were reported to receive the same index and reference tests (271 participants in total, 266 received OptMAL, 269 received Paracheck-Pf); the numbers presented in the analysis correspond.

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	**Commerical 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

Rakotonirina 2008 *(Continued)*

	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

Item	Authors' judgement	Description
Representative spectrum? All tests	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? All tests	Yes	Reference standard was PCR.
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	Stated that the PCR operator was blind to the results of the other tests performed.
Index test results blinded? All tests	Yes	Stated that the test readers were blind to the results of the other tests performed.
Uninterpretable results reported? All tests	Yes	There were no test failures with either RDT.
Withdrawals explained? All tests	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.

Ratsimbasoa 2007 *(Continued)*

	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

Ratsimbasoa 2007 *(Continued)*

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? All tests	Unclear	All participants were attending primary health centres with fever and symptoms of malaria, but the sampling method was not described.
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*

Ratsimbasoa 2008 *(Continued)*

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? All tests	Unclear	Participants were all attending a health centre with fever and typical symptoms of malaria, but the sampling method was not described.
Acceptable reference standard? All tests	Yes	The reference standard was PCR.

Ratsimbasoa 2008 *(Continued)*

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	PCR was carried out by technicians blind to the results of RDT testing.
Index test results blinded? All tests	Yes	RDTs were undertaken before the results of PCR were known
Uninterpretable results reported? All tests	Yes	Uninterpretable results are reported and excluded from the analysis. There were 2 invalid results for Bioline Pf and 1 for Bioline Pf/Pan.
Withdrawals explained? All tests	No	There was 1 participant missing from the analysis from Bioline Pf/Pan, with no explanation.

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.

Samane 2010 *(Continued)*

	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 Pv/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 **Who performed the index test, and where?** Not reported
Follow-up	Not applicable
Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Unclear	Characteristics of participants not adequately described, although all had symptoms of malaria.
Acceptable reference standard? All tests	Unclear	2 independent microscopists viewed the slides, but the number of fields viewed was not reported.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference tests.
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 test.
Reference standard results blinded? All tests	Yes	Reported that the tests were read blindly.
Index test results blinded? All tests	Yes	Reported that the tests were read blindly.
Uninterpretable results reported? All tests	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.
Withdrawals explained? All tests	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.

Selimuzzaman 2010

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

Selimuzzaman 2010 *(Continued)*

Notes	**Source of funding:** Not stated

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	Yes	Participants were a consecutive series of patients with clinical signs and symptoms of malaria.
Acceptable reference standard? All tests	No	One microscopist read each slide.
Partial verification avoided? All tests	Yes	All participants who received the index test also received the reference tests.
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 standards.
Reference standard results blinded? All tests	Unclear	Described as a single blinded study, but no further details reported.
Index test results blinded? All tests	Unclear	Described as a single blinded study, but no further details reported.
Uninterpretable results reported? All tests	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? All tests	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

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

Sharew 2009 *(Continued)*

	Age: All age groups eligible. Actual age range 6 months to 75 years. **Sex:** 361 (54%) males, 307 (46%) females **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. 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	**Commerical 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, Aklilu 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

Sharew 2009 *(Continued)*

Representative spectrum? All tests	Yes	Participants were a consecutive sample of febrile patients attending health centres with suspected malaria.
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.

Singh 2000a *(Continued)*

	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	**Commerical 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.
Incorporation avoided?	Yes	The index test does not form part of the reference standard.

Singh 2000a *(Continued)*

All tests		
Reference standard results blinded? All tests	Yes	"Blood films were examined...without reference to the results of ICT".
Index test results blinded? All tests	Yes	"All specimens were tested...who were blinded to the results of the blood smear tests".
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 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

Singh 2003 *(Continued)*

	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	**Commerical 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	Not applicable
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	Technican were blinded to the results of the blood smear examination.
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) (Zephyer Biomedicals Goa) • Falcivax Device (rapid test for malaria Pv/Pf) (Zephyer Biomedicals Goa) • Malascan Device (rapid test for malaria Pf/Pan) (Zephyer Biomedicals Goa), • ParaHIT Total (rapid test for Pf & Pan Malaria species) (SPAN Diagnostics Ltd, Surat) • 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

Singh 2010 *(Continued)*

- 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? All tests	Yes	Participants were a consecutive series of patients attending clinics with clinical signs and symptoms of malaria.
Acceptable reference standard? All tests	No	Only 1 microscopist used, except in cases of discordant results between microscopy and RDT.
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	Reported that the tests were read blindly.
Index test results blinded? All tests	Yes	Reported that the tests were read blindly.
Uninterpretable results reported? All tests	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? All tests	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 sub district, 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 **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

Tjitra 1999 *(Continued)*

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? All tests	Unclear	Participants were all attending a primary health care centre with fever and symptoms of malaria, but the sampling method was not described.
Acceptable reference standard? All tests	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.
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 microscopist was unaware of the immunochromatographic test result".
Index test results blinded? All tests	Yes	"The results were read by a study physician who was blinded to the microscopy results".
Uninterpretable results reported? All tests	Unclear	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? 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.

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

Trouvay 2013 *(Continued)*

	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	**Commerical 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 **Batch numbers:** not stated **Transport and storage conditions:** Tests were guaranteed to have been stored at the correct temperature (24 to 28C) and were used within their recommended shelf life. **Person(s) performing RDT:** Technician **RDT setting:** Cayenne Hospital
Follow-up	Not applicable
Notes	**Source of funding:** French Ministry of Health

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	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? All tests	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? All tests	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.

Trouvay 2013 *(Continued)*

All tests		
Incorporation avoided? All tests	Yes	The index test does not form part of the reference standard.
Reference standard results blinded? All tests	Yes	The microscopic examination was carried out simultaneously.
Index test results blinded? All tests	Yes	Interpretation of the test was carried out independently of the microscopic examination.
Uninterpretable results reported? All tests	Yes	No invalid RDTs were observed.
Withdrawals explained? All tests	Yes	There were 3 exclusions post-enrolment, due to *P. malariae* infection.

Valecha 2003

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.

Valecha 2003 *(Continued)*

	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	**Commerical 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

Table of Methodological Quality

Item	Authors' judgement	Description
Representative spectrum? All tests	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? All tests	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? 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	"Microscopists were blinded to the rapid test results".
Index test results blinded? All tests	Yes	The RDT was done before the microscopy.
Uninterpretable results reported? All tests	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? All tests	Unclear	The number of participants originally enrolled in the study was not explicitly stated; therefore it is unclear whether there were any withdrawals.

van den Broek 2006

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	**Commerical 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:**

van den Broek 2006 *(Continued)*

- Paracheck Pf - Type 1
- Parascreen - Type 3
- OptiMAL - Type 4

Batch numbers: Not stated

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? All tests	Unclear	All participants were patients presenting with suspected malaria, but the sampling method was not described.
Acceptable reference standard? All tests	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? 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	Report states that microscopists were blinded to the results of RDTs.
Index test results blinded? All tests	Yes	Report states that RDTs were blinded to the results of microscopy.
Uninterpretable results reported? All tests	Yes	There were no uninterpretable results; and weak lines were scored as positive.
Withdrawals explained? All tests	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.

Wongsrichanalai 2003

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 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?** 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	**Commerical 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

Wongsrichanalai 2003 *(Continued)*

Item	Authors' judgement	Description
Representative spectrum? All tests	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? All tests	Yes	2 independent microscopists at a research laboratory viewed at least 200 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	Yes	"read by two microscopists blinded to...the NOW ICT results".
Index test results blinded? All tests	Yes	The RDT was carried out before microscopy.
Uninterpretable results reported? All tests	Yes	The RDTs had to be repeated in 39 of 285 assays. A successful test was eventually completed for each sample.
Withdrawals explained? All tests	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

Xiaodong 2013 *(Continued)*

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?	Yes	Microscopy and PCR was used.

Xiaodong 2013 *(Continued)*

All tests		
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

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
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

Yan 2013 *(Continued)*

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 test
Differential verification avoided? All tests	Yes	The same reference test was used.
Incorporation avoided? All tests	Yes	The reference test was microscopy and PCR.
Reference standard results blinded? All tests	Yes	The microscopists were blinded to the results of additional diagnostic tests.
Index test results blinded? All tests	Yes	The readers of RDTs were blinded to the results of microscopy and PCR.
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.

Yan 2013 *(Continued)*

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.

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.
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.
Arcanjo 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.

Study	Reason for exclusion
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.
Baltzell 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.

Study	Reason for exclusion
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.
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	Reason for exclusion
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.
Deletoille 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.
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.

Study	Reason for exclusion
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 assymptomatic 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.
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.

Study	Reason for exclusion
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.
Gomes 2013	Selected positve 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.

Study	Reason for exclusion
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.
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.

Study	Reason for exclusion
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.
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.

Study	Reason for exclusion
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.
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 diganostic 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.

Study	Reason for exclusion
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.
Miantuasila 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.

Study	Reason for exclusion
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.
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.
Nicastri 2009a	No data presented on non-falciparum malaria.
Nigussie 2008	No data presented on non-falciparum malaria.
Nkrumah 2010	RDT evaluated is not an immunochromatographic test.

Study	Reason for exclusion
Nkrumah 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 postives, 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.
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.

Study	Reason for exclusion
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.
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.
Rehlis 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.

Study	Reason for exclusion
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.
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 parasitiaemia 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.

Study	Reason for exclusion
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.
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.
Sotimehin 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 an endemic to a non-endemic area.

Study	Reason for exclusion
Stephens 1999	No data presented on non-falciparum malaria.
Stow 1999	No data presented on non-falciparum malaria.
Strøm 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.
Trachsler 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.
Valéa 2009	No data presented on non-falciparum malaria.
Van den Ende 1998	Participants were travellers returning from endemic to non-endemic areas.

Study	Reason for exclusion
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 Hellemond 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.
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.

Study	Reason for exclusion
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.

Table 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
17 Non-falciparum species only, microscopy, Other Type, Malariagen Malaria	1	262

Test	No. of studies	No. of participants
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.

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

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

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

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

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

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

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

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

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

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

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

Test 13. Non-falciparum species only, microscopy, Type 4, OptiMAL.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Test 28. *P. vivax,* microscopy, Pf HRP-2 and Pv pLDH, Pf/Pv Malaria Device.

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

Test 30. *P. vivax*, PCR, Pf HRP-2 and Pv pLDH, Falcivax.

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

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

Test 33. *P. vivax,* PCR, Pf HRP-2 and Pv pLDH (All).

Test 34. *P. vivax*, PCR, Type 6, PALUTOP (All).

ADDITIONAL TABLES

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)

Table 2. Malaria 'zones' by endemic parasite species and type of test appropriate for each *(Continued)*

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

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

Singh 2010	Malascan	18	67	33
Tjitra 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
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 3 tests				
Ashton 2010	Carestart	37	22	78
Ashton 2010	Parascreen	43	14	86
Bendezu 2010	Parascreen	19	84	16
Bharti 2008	First response	7	100	0
Dev 2004	Diamed OptiMAL	3	100	0
Eibach 2013	CareStart	3	100	0
Elahi 2013	Parascreen	5	60	40
Kosack 2013	SD Bioline	133	89	11
Moges 2012	Carestart	38	89	11
Ratsimbasoa 2007	SD Malaria Antigen Bioline	4	100	0
Singh 2010	Parascreen	13	54	46
Singh 2010	First response	9	33	67
Singh 2010	ParaHIT Total	48	92	8
Trouvay 2013	SD Malaria Ag Pf/Pan	18	78	22
Yan 2013	Pf/Pan Device	24	25	75
Median (range)			84 (14 to 100)	16 (0 to 86)
Pooled estimate (95% CI)			74 (52 to 88)	26 (12 to 48)
Type 4 tests				
Andrade 2010	OptiMAL-IT	0	0	0
Chayani 2004	OptiMAL	3	100	0

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

Dev 2004	SD Malaria	2	100	0
Kolaczinski 2004	OptiMAL	23	100	0
Metzger 2011	OptiMAL-IT	30	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)			100 (0 to 100)	0 (0 to 67)
Pooled estimate (95% CI)			87 (79 to 92)	13 (8 to 21)

*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[1]
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)	

[1]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 Ratio of specificity (95% CI),		Type 2	Type 3
	Studies (participants)	11 (6879)	23 (11,234)

Table 6. Comparisons of RDT types for non-falciparum infections verified by microscopy *(Continued)*

			P value for comparison	
	Studies (participants)	**Sensitivity (95% CI)**	78 (73 to 82)	78 (69 to 84)
		Specificity (95% CI)	99 (97 to 99)	99 (98 to 99)
Type 2	11 (6879)	78 (73 to 82)	-	-
		99 (97 to 99)		
Type 3	23 (11,234)	78 (69 to 84)	1.00 (0.89 to 1.12), P = 1.00	-
		99 (98 to 99)	1.00 (0.99 to 1.01), P = 0.87	
Type 4	10 (3831)	90 (79 to 95)	0.87 (0.78 to 0.96), P = 0.01	0.87 (0.76 to 0.99), P = 0.03
		98 (97 to 99)	1.00 (0.99 to 1.02), P = 0.52	1.01 (1.00 to 1.02), P = 0.29

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

(Continued)

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?

(Continued)

	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.
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.

(Continued)

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. • '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.
Are the index test results blinded?	• '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. • '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.
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. • '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. We reported how many results were uninterpretable (of the total) and how these were handled in the analysis.
Were any withdrawals explained?	• '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. • '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 participants were excluded from 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 versus Type 3								
	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
Type 2 versus Type 4								
	Type 2	**Type 4**			**Type 2**	**Type 4**		
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
Type 3 versus Type 4								
	Type 3	**Type 4**			**Type 3**	**Type 4**		
Dev 2004	71 (5/7)	90 26/29	-18.2 (-53.5 to 17.0)	P = 0.24	100 (23/23)	100 (111/111)	0 (Not estimable)	Not estimable
Ratsimbasoa 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)	1	179	91 (81 to 97)	100 (97 to 100)
Type 3, Parascreen	14	5407	79 (67 to 88)	98 (98 to 99)	2	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)	1	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)	1	196	64 (41 to 83)	99 (97 to 100)
Type 4, OptiMAL	6	1843	90 (85 to 93)	98 (97 to 99)	1	313	88 (64 to 99)	98 (96 to 99)

WHAT'S NEW

Date	Event	Description
16 April 2015	Amended	Errors in the number of malaria cases were corrected in the Summary of Findings table.

CONTRIBUTIONS OF AUTHORS

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

DECLARATIONS 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.

SOURCES OF SUPPORT

Internal sources

- International Medical University, Malaysia.

  Research grant ID 134/2007
- Liverpool School of Tropical Medicine, UK.

External sources

- Department for International Development, UK.

  Research Programme Grant

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.

INDEX TERMS

Medical Subject Headings (MeSH)

Antigens, Protozoan [*analysis]; Cohort Studies; Malaria [*diagnosis] [immunology] [parasitology]; Malaria, Vivax [*diagnosis] [immunology]; Microscopy; Parasitemia [diagnosis]; Plasmodium [*immunology]; Plasmodium vivax [immunology]; Polymerase Chain Reaction; Reagent Kits, Diagnostic [*parasitology]; Sensitivity and Specificity; Species Specificity

MeSH check words

Humans