PERFORMANCE OF THE OPTIMAL® ASSAY FOR DETECTION AND IDENTIFICATION OF MALARIA INFECTIONS IN ASYMPTOMATIC RESIDENTS OF IRIAN JAYA, INDONESIA

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Abstract. The OptiMAL® assay, a new immunochromatographic “dipstick” test for malaria based on detection of Plasmodium lactate dehydrogenase (pLDH), is purported to detect infections of ~200 parasites/µL of blood and to differentiate between Plasmodium falciparum and non-P. falciparum. We evaluated OptiMAL® performance by comparing the test strip interpretations of two independent readers with consensus results obtained independently by expert malaria microscopists. Unbiased measures of sensitivity were derived by applying the OptiMAL® test for detection and differentiation of light, asymptomatic infections by P. falciparum and Plasmodium vivax. OptiMAL® readings were separated in time to determine whether the reaction signal was stable. Microscopy identified infections in 225 of 505 individuals screened; those with P. falciparum (n = 170) averaged 354 asexual forms/µL and P. vivax/Plasmodium malariae (n = 112) averaged 216 asexual forms/µL of blood. Concordance between OptiMAL® and microscopy was 81% and 78% by the two independent readings. The assay’s sensitivity for detection of any malaria species was 60.4% and 70.2% respectively and specificity was 97% and 89%. Most cases identified by microscopy as P. falciparum were graded as negative or non-P.falciparum by both OptiMAL® readers. OptiMAL® false negatives as well as misidentifications were related to low parasitemias (< 500/µL). The OptiMAL® assay demonstrated 88–92% sensitivity for detecting infections of 500–1,000 parasites/µL, a range covering the mean parasitemia of primary symptomatic P. falciparum infections in malaria-naïve Indonesian transmigrants. This device was markedly less sensitive than expert microscopy for discriminating between malaria species and is presently unsuited for use as an epidemiological screening tool. The OptiMAL® assay is not approved for diagnostic use but is commercially available for research purposes only.

INTRODUCTION

Light microscopic inspection of Giemsa-stained blood films remains the standard method for the diagnosis of malaria, a disease threat confronting almost 40 percent of the human population daily and causing an estimated 300 to 500 million new infections each year.¹ The diagnosis of malaria by microscopy of Giensa-stained blood smears is a labor-intensive method that requires quality staining, precision microscopes, and trained, experienced microscopists. These limitations have prompted research and development of simple, rapid, non-microscopical diagnostic tests to detect the presence of malaria parasites at levels of accuracy comparable to those of a skilled microscopist.

Flow Inc., a Portland, Oregon-based biotechnology firm, received funding from the US Department of Defense for the development of a rapid, sensitive, immunochromatographic assay based upon the detection of malaria-specific lactate dehydrogenase (pLDH), an enzyme whose isoforms are produced by the living parasites. A prototype dipstick product, the OptiMAL® assay, purportedly enables fast differential identification of Plasmodium falciparum and non-falciparum malaria in blood at levels of detection similar to microscopy. Preliminary field testing has indicated ~95% sensitivity for infections of ~200 parasites per microliter and a lower rate of false positives than has been reported for rapid tests based on detection of histidine-rich protein 2 (HRP-2).² Because pLDH is a product of viable parasites and not a residual metabolite such as HRP-2, the OptiMAL® assay might be a simple way to monitor parasite in vivo response following drug therapy if it is sufficiently sensitive to detect the progressive decline or resurgence of low-level parasitemias.

The OptiMAL® assay uses a pan-specific 6C9 murine monoclonal antibody conjugated to colloidal gold to bind isoforms of pLDH in lysed blood and a set of capture antibodies immobilized as bands on a nitrocellulose dipstick to selectively trap the upwardly migrating color-bound pLDH. A P. falciparum infection is indicated by color development at the zones of the P. falciparum-specific 17E4 and the panspecific 19G7 antibodies. A non-P. falciparum malaria infection is indicated by color development only at the pan-specific 19G7 antibody band.³

As with other malaria rapid dipstick assays currently available, the cost of the OptiMAL® assay would be initially high and probably limited to use in military, expatriate, and traveler populations. However, the malaria-naïve status of these groups makes them susceptible to illness at very low parasitemias, thus challenging the sensitivity of the new assay. To determine the lower limits of sensitivity as well as the specificity and stability of the OptiMAL® test, we compared its performance to expert microscopy for detection of P. falciparum and Plasmodium vivax malaria in an active-case detection screening of asymptomatic populations living in Irian Jaya, Indonesia. Our rationale was to avoid bias stemming from a knowledge of clinical illness and to permit assessment of the new test against a range of light, naturally occurring, and genetically diverse malaria infections.

MATERIALS AND METHODS

Study sites and subjects. All active-case detection screening for malaria infection was performed in Armapa on northeast coastal Irian Jaya, Indonesia during November, 1997. Tandem screening by microscopy and OptiMAL® as-
say was performed on 276 native Irianese with life-long malaria exposure and 232 Indonesian transmigrants who had lived in Irian Jaya for 12 to 30 months. Subjects screened by the two methods reported no malaria-like illness at the time of blood sampling.

The geometric mean (GM) parasitemia of primary P. falciparum and P. vivax infections associated with clinical illness was derived from expert microscopy routinely applied to self-reported symptomatic cases in a population of 246 non-immune Javanese children and adults during their first year of residence (October 1996–October 1997) in the Ar- mopa SP2 settlement.

Informed consent was obtained from all subjects and from the parents of participating children. Treatment was provided to all symptomatic cases according to standard Indonesian health policy or the approved malaria research protocol that volunteers had been enrolled in. This research was approved by institutional review boards of the US Naval Medical Research Unit No. 2, Jakarta, Indonesia; the US Naval Medical Research Institute, Bethesda, Maryland; and the National Institute of Health Research and Development (PPM, LIT-BANGKES), Jakarta, Indonesia. This work was conducted in accordance with US Navy and Republic of Indonesia regulations governing the protection of human subjects in medical research. American and Indonesian committees for the protection of human subjects reviewed and approved the procedures followed in this research (Protocols DOD#30820 and DOD#30836).

**Malaria diagnosis by microscopy.** Sterile lancets were used to obtain finger- or heel-stick blood from consenting individuals. All individuals were given ordinal study numbers and a record was made of their name, age, address, and response to the query: “Do you feel ill?” Blood smears were made onto pre-cleaned slides marked with the subject’s name, study number, and date. Slides were marked with an asterisk to denote illness and insure prompt reading. Air-dried thick and thin blood films were stained within 6 hours with freshly prepared 2% Giemsa stain in pH 7.2 phosphate buffered saline. Stained slides were examined under a compound light microscope using 1,000× oil immersion magnification. A maximum of 300 thick film fields was read before a slide was judged negative. All parasites were enumerated against 200 white blood cells. Slides were reexamined in the same way by a second microscopist, and in cases of discordance, by a third microscopist. Microscopy was performed by experts with at least 10 years of experience. Species identification was based on morphology with agreement between two independent microscopists.

**Malaria diagnosis by OptiMAL® assay.** OptiMAL® testing was performed on finger-prick blood from the same lancet wound from which malaria smears were made. An OptiMAL® test strip was labeled with the study subject’s name and slide/study number. After malaria smears had been made, a calibrated micropipettor was used to collect a 10 μL volume of blood. This was immediately transferred to a 12 × 45 mm glass tube containing 2 drops (~30 μL) of OptiMAL® buffer solution A. The blood and buffer solution were mixed and an OptiMAL® test strip was added to the tube. A standard duration of 15 minutes was allowed for the sample to wick-up completely into the test strip. The test strip was then transferred to a clean glass tube containing 4 drops (~60 μL) of OptiMAL® buffer solution B and allowed to clear completely of background blood pigment for 10 to 15 minutes. Cleared strips were read in natural daylight and the results were recorded. One technician performed all OptiMAL® assays and readings in the field. Another techni- cian reread the same OptiMAL® strips 5 months later. Polymerase chain reaction (PCR) employing species-specific P. falciparum and P. vivax oligonucleotide primers complementary to the small subunit rRNA gene and published methodology4 was applied to a sample of discordant microscopy/OptiMAL® results to validate the accuracy of consensus microscopy.

**Data analyses.** OptiMAL® sensitivity and specificity calculations were based upon malaria slide readings that had been confirmed blindly by two expert microscopists. Asexual-stage parasite counts per microliter of blood were estimated by multiplying the count per 200 white blood cells by a conversion factor of 40, assuming an average of 8,000 lymphocytes/μL of blood.7 These counts were log transformed to normalize the distribution and allow for between group-reader comparison by analysis of variance. Between-group analyses compared GM parasite densities in cases of concordance and discordance between microscopy and OptiMAL® results. Using confirmed microscopy as the standard comparator, proportional analyses of correct identifications in each range were also made between OptiMAL® readers for the two parasite species. The z-test was used for comparing proportions of correct and incorrect malaria diagnoses relative to consensus microscopy and P values < 0.05 were indicative of statistically significant differences.

**RESULTS**

**Malaria prevalence determined by microscopy.** Concordant results between independent microscopists yielded a collection of 276 slides from native Irianese and 229 slides from Javanese transmigrants. Parasitemias were detected in 40.2% and 49.8% of these respective groups. Among Iri-anese, 90 of 111 infections were by P. falciparum; 20 of these were mixed infections with P. vivax, P. malariae, or both. Eighty of 114 infections among Javanese transmigrants were by P. falciparum; 37 of which were mixed infections with P. vivax. The overall GM parasitemia was 377 parasites/μL (P. falciparum 354/μL versus P. vivax/P. malariae 216/μL; P = 0.04).

**Comparison of Optimal® and microscopy results.** Using the consensus microscopy results as the standard, concordance between Optimal® and microscopy was 81% (408/505) and 78% (392/505) by the two Optimal® readers. Sensitivity of Optimal® for detection of any malaria infection in the combined populations was 60.4% and 70.2% by the two readers (Table 1). Specificity was 97.1% and 83.6% respectively. The overall level of sensitivity achieved by the second reader was significantly higher (P = 0.03) than the first but at a cost of significantly lower specificity and positive predictive value (P < 0.001). Sensitivity levels determined by the two Optimal® readers for detection of any malaria in the Javanese subsample were nearly identical (P = 0.88); between-reader differences in specificity (P = 0.004) and specificity (P < 0.001) for the Irianese subsample were highly significant.
TABLE 1
Comparison of OptiMAL® and microscopy results for the detection of malaria infection

<table>
<thead>
<tr>
<th></th>
<th>Microscopy</th>
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<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
<td>Total</td>
</tr>
<tr>
<td>OptiMAL® Reader #1*</td>
<td>136</td>
<td>8</td>
<td>144</td>
</tr>
<tr>
<td>Positive</td>
<td>89</td>
<td>272</td>
<td>361</td>
</tr>
<tr>
<td>Negative</td>
<td>225</td>
<td>280</td>
<td>505</td>
</tr>
<tr>
<td>OptiMAL® Reader #2†</td>
<td>158</td>
<td>46</td>
<td>204</td>
</tr>
<tr>
<td>Positive</td>
<td>67</td>
<td>234</td>
<td>301</td>
</tr>
<tr>
<td>Negative</td>
<td>225</td>
<td>280</td>
<td>505</td>
</tr>
</tbody>
</table>

* Sensitivity = 136/225 = 60.4%; Specificity = 272/280 = 97.1%; Positive Predictive Value = 136/144 = 94.4%; Negative Predictive Value = 89/361 = 24.6%.
† Sensitivity = 158/225 = 70.2%; Specificity = 234/280 = 83.6%; Positive Predictive Value = 158/204 = 77.4%; Negative Predictive Value = 67/301 = 22.2%.

Figure 1 shows that among asymptomatic carriers, the majority of cases identified and confirmed by microscopy as *P. falciparum* were misidentified by both OptiMAL® readers as non-*falciparum* malaria. By contrast, the two OptiMAL® readers identified only one of 52 microscopy-confirmed *P. vivax/P. malariae* cases as *P. falciparum*; the majority graded either as negative (56%, 46%) or correctly as non-*P. falciparum* (42%, 52%). Thirty-one cases of discordance between consensus microscopy and OptiMAL® were tested by PCR. There was 84% concordance between consensus microscopy and PCR (2 cases that microscopists identified as *P. falciparum* were PCR positive for *P. vivax*, 1 case designated *P. vivax* was PCR positive for *P. falciparum*, and 2 cases of PCR-confirmed *P. falciparum* were called negative by 2 of 3 microscopists). Concordance between OptiMAL® readers and PCR was 3% and 10%.

Among asymptomatic carriers of *P. falciparum* or *P. vivax*, the majority of OptiMAL® false negatives were related to low parasitemias. Figure 2 plots the geometric mean parasitemias of confirmed *P. falciparum* infections by OptiMAL® category and shows that in immune Irianese and partially-immune transmigrants, *P. falciparum* parasitemias under 300 parasites/μL were graded as OptiMAL® negative; those ranging from 200–600 parasites/μL were graded as non-*P. falciparum* (*P. vivax/P. malariae*); and those > 600 parasites/μL were correctly identified as *P. falciparum*. Differences between OptiMAL® sensitivity in the two subsamples relates to the higher proportion of malaria infections in Javanese (*P = 0.03*) and differences in the GM parasitemias (Javanese GM = 398 parasites/μL versus Irianese GM = 282 parasites/μL, *P = 0.09*).

Infections correctly identified by both OptiMAL® readers as *P. falciparum* ranged from < 40 to 8,953 parasites/μL and averaged 1,140 and 895 parasites/μL, respectively. Infections correctly identified by both OptiMAL® readers as *P. vivax/P. malariae* ranged from 80 to 8,912 parasites/μL and averaged 359 and 300 parasites/μL, respectively. Differences between these means were not significant. The highest confirmed *P. falciparum* infections incorrectly graded as OptiMAL® negative were 2,042 parasites/μL (Reader #1) and 3,162 parasites/μL (Reader #2); those incorrectly graded as non-*P. falciparum* by OptiMAL® test were at the levels of 5,000 parasites/μL (Reader #1) and 3,724 parasites/μL (Reader #2). The highest *P. vivax* infection graded OptiMAL® negative by both readers was 681 parasites/6L. There was no apparent correlation between parasitemia and intensity of the *falciparum*-specific 17E4 color band. The most intense reaction was observed in an Irianese subject with 560 *P. falciparum* rings/μL. All reacted test strips showed a clear LDH control band.

Figure 3 plots the GM parasitemias by sequence of occurrence of symptomatic malaria infections in non-immune Javanese transmigrants. It shows a lower symptom threshold for *P. vivax* than for *P. falciparum* and a progressive heightening of symptom threshold for both types of malaria infection. The 95% confidence interval (CI) around GM parasitemias in primary symptomatic infections by *P. falciparum* is within the range of parasitemias accurately identified by the OptiMAL® test as *P. falciparum*. The pan-specific 19G7 band was reactive and visible for malaria infections that were significantly lower than the mean parasitemia of pri-

FIGURE 3. Geometric mean (GM) parasitemias of symptomatic malaria in non-immune Indonesian transmigrants plotted by sequence of infection. NV1, NV2, and NV3 = 1st, 2nd, and 3rd new *Plasmodium vivax* infections; NF1, NF2, and NF3 = 1st, 2nd, and 3rd new *Plasmodium falciparum* infections. CI = confidence interval.
mary symptomatic *P. falciparum* infections in malaria-naive transmigrants (389 versus 1,002 parasites/µL; *P* < 0.001). This range for accurate OptiMAL® detection of any *Plasmodium* species is also within the 95% CI around the GM parasitemia of primary symptomatic cases of *P. vivax* in these non-immune individuals.

Confirmed parasitemias tabulated by species, density, and OptiMAL® grade are presented in Table 2. As expected, OptiMAL® sensitivity for detection of any malaria increased with higher parasitemia, attaining > 95% for both readers when density exceeded 500 parasites/µL (0.01%). The trend evident in identifications by both OptiMAL® readers was the failure to see the *falciparum*-specific 17E4 reaction band in the majority of parasitemias confirmed by microscopists as *P. falciparum*. There were no significant between-reader differences (*P* > 0.17) in the proportions of correct OptiMAL® identifications of *P. falciparum* and non-*P. falciparum* (*P. vivax/P. malariae*) made at any of the 6 parasitemia ranges studied.

**Procedural aspects of the OptiMAL® assay.** In practice, field conduct of the OptiMAL® test was rapid and simple. Sequential batches of 12 samples per batch were easily managed by one person. The OptiMAL® assay was initially performed in the plastic microtiter wells provided in the kit, and reacted test strips were read after the directed 2 to 5 minute clearing period. However, upward wicking of sample lysate from microtiter wells appeared to be slow within the 15-minute maximum reaction time specified by the manufacturer, and subsequent clearing of heme pigment from the reacted strip was not achieved within the prescribed 2 to 5 minutes. Complete, even wicking of the sample was obtained when the test strip reactions were performed in 12 × 45 mm glass tubes. Tubes held upright in a rack or holder were also more stable than the shallow microtiter plate for managing batches of test strip. The tubes provided an additional or confirmatory site for noting identifications and/or times. Although reaction lines for strong positives do become visible after 2 minutes of clearing, the clearing process should continue longer to prevent heme from leaching back onto the reaction lines of the strip. A standard 15 minutes of clearing time was applied to achieve complete clearance of heme from reacted OptiMAL® strips, sufficient to see faint reaction lines against a clean white background. Preliminary results and observations were communicated to the OptiMAL® manufacturer in order to assist in the refinement of this product.

**DISCUSSION**

Despite the overall low level of parasitemias in this study, there was reasonably high concordance between microscopy and the OptiMAL® assay in readings made both in the field and 5 months later with no significant between-reader differences in sensitivity or specificity. These results indicate the reproducibility of OptiMAL® results between readers and the durability of its reaction signal over time. It seems possible that OptiMAL® interpretations may have been improved by reading the reacted cleared test strips after complete drying.

In our test populations the OptiMAL® assay demonstrated 88% and 92% sensitivity for the detection of malaria parasitemias of 500 to 1,000 parasites/µL (0.01–0.02%). This sensitivity is sufficient to detect most primary symptomatic *P. falciparum* infections that occur in malaria-naive Indonesian transmigrants during their first year of residence in Irian Jaya. Below this, in parasitemias of 200 to 499 asexual forms/µL (0.004–0.01%), a range that was convergent with the mean of primary symptomatic *P. vivax* infections in this naive population (406 parasites/µL; 95% CI: 325–508 parasites/µL), the OptiMAL® assay demonstrated sensitivity of 58% and 68%. Similar findings of good sensitivity (> 88.2%) for parasitemias > 0.01% and a marked decrease in sensitivity for those below 0.01% have been reported from an OptiMAL® evaluation conducted in the Gambia.

Unlike previously published studies that have evaluated OptiMAL® performance against predominantly *P. vivax* infections in clinically ill patients, more than three-quarters of our study population was infected by *P. falciparum* with a mean parasitemia significantly greater than that of non-*P. falciparum* infections. Given this weighting and an expectation of ~96% OptiMAL® sensitivity for *P. falciparum* parasitemias of ~500 parasites/µL, we are discouraged by the low frequency with which both OptiMAL® readers accurately discerned *P. falciparum* infections and the high frequency and density of *P. falciparum* infections that they graded as non-*P. falciparum*. Among 64 confirmed parasitemias of > 500 trophozoites/µL attributed to *P. falciparum* alone, OptiMAL® readers correctly identified 48–58% as *P. vivax/P. malariae*. }

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**Table 2**

Microscopy-confirmed malaria infections tabulated by parasite density range, species, and grading by two independent OptiMAL® readers

<table>
<thead>
<tr>
<th>No. asexual parasites/µL of blood</th>
<th><em>Plasmodium falciparum</em></th>
<th><em>Plasmodium vivax/P. malariae</em></th>
<th>OptiMAL® Reader #1</th>
<th>OptiMAL® Reader #2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1–99 (&lt;0.002%)</td>
<td>13 (30.9)</td>
<td>4 (16.7)</td>
<td>7 Pf; 9 Pv/Pm</td>
<td>7 Pf; 14 Pv/Pm</td>
</tr>
<tr>
<td>100–199 (0.002–0.004%)</td>
<td>10 (52.6)</td>
<td>8 (66.7)</td>
<td>1 Pf; 9 Pv/Pm</td>
<td>8 Pf; 6 Pv/Pm</td>
</tr>
<tr>
<td>200–499 (0.004–0.01%)</td>
<td>28 (62.2)</td>
<td>4 (57.1)</td>
<td>1 Pf; 27 Pv/Pm</td>
<td>5 (71.4)</td>
</tr>
<tr>
<td>500–999 (0.01–0.02%)</td>
<td>20 (95.2)</td>
<td>7 (71.4)</td>
<td>13 Pf; 7 Pf/Pm</td>
<td>7 Pf; 13 Pf/Pm</td>
</tr>
<tr>
<td>1,000–1,999</td>
<td>17 (94.4)</td>
<td>10 (75.0)</td>
<td>3 Pf/Pm</td>
<td>12 Pf; 6 Pf/Pm</td>
</tr>
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</table>

*Pf* = *Plasmodium falciparum*; *Pv* = *Plasmodium vivax*; *Pm* = *Plasmodium malariae*. 

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**FIELD PERFORMANCE OF MALARIA RAPID DIAGNOSTIC ASSAY**

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falciparum, graded an additional 39–47% as P. vivax/P. malariae, and read 3–5% as negative. There were relatively few asymptomatic parasitemias by P. vivax in this higher density range but OptiMAL® readers reported 78–89% of these infections. Such results, if unchallenged and based upon one microscopist or one OptiMAL® reader, might be questioned on grounds of human error. Differences in the experience and accuracy of microscopists in detecting and differentiating infections as well as the method employed for quantifying parasitemias make for difficulties in comparing OptiMAL® sensitivities obtained by different investigators.7,9

Our application of PCR analysis to a small sample of discordant samples aptly supported the competence of our expert microscopists, a team with over 40 years of collective experience. Differences in sensitivity may be partly due to disparities in the expertise of each investigation’s standard. Additionally, parasite enumeration based on thick smear counts per 200 leukocytes in capillary rather than venous blood with an assumption of 8,000 leukocytes/µL, may have contributed to reduced sensitivity. Another complicating factor may have been the unreported prior use of antimalarial drugs, resulting in remnant but non-viable pLDH negative parasitemias. We did not obtain evidence from our two sample populations to suggest that pre-existing anti-pLDH antibodies interfered with or reduced OptiMAL® detection of malaria.

In previous evaluations of rapid diagnostic modalities for malaria, we speculated on phenotypic variations in parasites and host metabolic and/or immune factors that could reduce target antigens or interfere with their binding to detecting antibodies.10 Consideration might also be given to the polyvalent capacity or enhanced binding affinity of the pan-specific 6C9 and 19G7 antibodies over that of the falciparum-specific 17E4 antibody employed in the OptiMAL® assay as a possible explanation for the relative inability of our test readers to detect the 17E4 signal in many P. falciparum infections. Within- and between-species differences in pLDH expression and binding epitope availability may be determinants. Among the four species of human malaria detectable by pLDH-mediated conversion of 3-acetyl pyridine adenine dinucleotide (APADH) to APADH, P. falciparum was reported to have a pLDH detection threshold more than five times higher than that of P. vivax. Investigators who found no correlation between pLDH levels and parasite concentrations, reported undetectable levels of pLDH in patients with P. falciparum counts that ranged up to 13,000 parasites/µL and calculated the diagnostic sensitivity of the “wet” assay to be 76%.11 Although in vitro testing with the 19G7 pan-specific antibody has shown pLDH from P. vivax strains to have lower specific activity of pLDH than any of 6 strains of P. falciparum tested,1 it has been reported for mixed P. falciparum plus P. vivax infections that the OptiMAL® pan-specific 19G7 band developed a more intense darker color than the 17E4 falciparum-specific band.7

It should be recognized that the OptiMAL® assay is a research device not yet approved for sale or use as a diagnostic test. As such, the test strips we evaluated were not produced under the strict standards of good manufacturing practice (GMP) and may have differed in quality from those tested by other laboratories. The new immunochromatographic assays based on pLDH that are being refined for rapid detection, differentiation, and monitoring of parasite response to therapeutics are very promising and may find life-saving applications in military and civilian health services. We have endeavored to provide a critical evaluation of the OptiMAL® assay and to support the developer’s further improvement of this product and its procedure.

In summary, the OptiMAL® assay has some capacity to detect the light parasitemias that induce symptoms in malaria-naïve individuals. However, in the range of asymptomatic parasitemias studied, we found it markedly less sensitive than expert microscopy for reliable detection or species discrimination and consider this device presently unsuited for use as an epidemiological tool.

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Disclaimer: The views of the authors expressed herein do not purport to reflect those of the US Navy, the US Department of Defense, the Indonesian Ministry of Health, or Flow Inc.

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