RAPID DIAGNOSTIC DEVICES FOR MALARIA: FIELD EVALUATION OF A NEW PROTOTYPE IMMUNOCHROMATOGRAPHIC ASSAY FOR THE DETECTION OF PLASMODIUM FALCIPARUM AND NON-FALCIPARUM PLASMODIUM


The NOW® ICT Malaria P.f./P.v. for Whole Blood (Binax, Inc., Portland, ME) is a new malaria rapid diagnostic device that represents a technical advance over previous assays, such as ICT™ Malaria P.f./P.v. and ICT™ Malaria P.f.. We evaluated this device in March 2001 in symptomatic patients at malaria clinics in Maesod, Thailand. Microscopic examination of Giemsa-stained blood smears was the reference standard. In 246 patients, microscopy showed 32 (13.0%) infected with *Plasmodium falciparum*, 63 (25.6%) with *P. vivax*, 6 (2.4%) with mixed infections of *P. falciparum* and *P. vivax*, 5 (2.0%) with *P. malariae*, and 140 (56.9%) negative. Sensitivity for *P. falciparum* was 100% and specificity was 96.2% (200 of 208; 95% confidence interval [CI] = 92-98). For *P. vivax*, sensitivity was 87.3% (55 of 63; 95% CI = 77-93) and specificity was 97.7% (173 of 177; 95% CI = 95-99), but all the four false-positive results were microscopically positive for *P. malariae*; thus, specificity for non-falciparum Plasmodium was 100%. These results suggest improved performance over NOW® ICT predecessors.


RAPID DIAGNOSTIC TESTING FOR MALARIA

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Malaria rapid diagnostic devices (MRDD) have been developed with the hope that they would offer accurate, reliable, rapid, cheap and easily available alternatives to traditional methods of malaria diagnosis. The results from early malaria rapid diagnostic studies were quite promising, especially for detecting *Plasmodium falciparum* at densities of more than 100–500 parasites/µl. Despite the introduction of these devices over a decade ago, only a few target antigens have been introduced. Of greater concern, these devices have shown limitations in sensitivity, ability to differentiate species and robustness under field conditions in the tropics. Recent trials have revealed wide variability in sensitivity both within and between products. We review the recent trials assessing MRDD use for the diagnosis of *P. falciparum* and non-*P. falciparum* infections in endemic and non-endemic countries and describe the various aspects of these devices which need further improvement. High quality, accurate, rapid and affordable diagnostic tools are urgently needed now that new antimalarial regimens, characterized by higher cost and increased toxicity, have been introduced more widely in response to emerging multi-drug resistance.

Tropical Medicine and International Health 2003; 8(10): 876-83.