Summary Table

| Detection of Histidine Rich Protein 2 and Pan malarial ICT malaria Pf/Pv test antigens after chloroquine treatment of uncomplicated falciparum malaria does not reliably predict treatment outcome in Eastern Indonesia | Emiliana Tjitra, Sri Suprianto, Mary E. Dyer, Bart J. Currie and Nicholas M. Anstey  
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<tr>
<td>RDT product(s):</td>
<td>ICT Pf/Pv test kits, AMRAD ICT, Sydney, Australia; MI .02 lot 041 388</td>
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<td>Target antigens:</td>
<td>ICT :HRP 2 and pan malaria</td>
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<td>Comparative standard(s):</td>
<td>Microscopic examination of Giemsa stained thin/thick blood films</td>
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| Trial type: Accuracy / Cost-benefits/ public health impact /ease of use / behavioral: | • Longitudinal study of post treatment failure detection using RDT  
• Cost benefits not considered  
• Increased ability to recognise drug resistant malaria  
• No comment on ease of use /No behavioural changes recommended |
| *Usefulness of paper (rated by reviewers): | 4 |
| Major findings/implications: | • Post treatment testing for HRP-2 and pan-malaria antigen cannot reliably predict TF  
• Negative RDT for these antigens was less predictive of adequate clinical response  
• Persistence of HRP-2 antigenaemia after clearance of asexual stages, results in false positivity and suboptimal accuracy in prediction of treatment outcomes  
• False negative results may result from failure to detect low levels of antigenaemia  
• Gametocytaemia (post SP and Chloroquine treatment) can prolong the detection of pan malaria antigen |

Country: Indonesia

Trial type

This was a longitudinal study to evaluate the utility of HRP2 and pan malaria antigen detection in predicting the outcome of chloroquine therapy of uncomplicated malaria. The study was carried out in Radamata Health Centre, Laratama sub district, Nusa Tenngara Timur province, Indonesia, an area of hypo-endemic malaria as part of a broader study evaluating the diagnosis and treatment of malaria in areas of different endemicity.

The immunochromatographic RDT’s under evaluation are

- ICT malaria Pf/Pv for HRP 2 and pan antigen detection obtained from AMRAD ICT, NSW,Australia MI .02 lot 041388.
  Test lots were used according to manufacturers’ instructions by experienced health care staff and additional training in standardised comparison of the RDT test line intensity compared to the control line was made. Storage conditions or additional requirements for blood collection or test performance were not stated. Readers of Giemsa stained blood slides were an experienced microscopist from the National referral centre who examined 100 fields of a thick film. Discordant result were referred to a second referral centre where 200 fields of a thick film were examined and 10% of concordant results confirmed. No record of ‘blinding’ of microscopist’ results or inter observer variation was made.

No local laboratory or climatic conditions were described by the authors.
**Results and analysis:**

Analysis was made using Epi Info 6 system (CDC, Atlanta, GA) The denominator used on each day of follow up was the number of patients from whom a Pf/Pv result was available. Based on predictive outcome ICT Pf/Pv was classified as True positive, false positive or true negative, false negative and the PPV calculated as TP (TP+TN) and NPV as TN (TN+FN).

Predictive accuracy was defined as (TP+TN)/number of tests performed on that day of follow up.

66 febrile patients with uncomplicated malaria were included in the study with parasite densities from 1,160-32400/µL and clinical and laboratory data for blood films and RDT was collected at 0, 1, 2, 3, 7, 14, and 28 days and at any time when patient became unwell. Treatment failure was defined for this period. Graphical comparative data on Positive predictive values and Negative predictive values for TF from blood film reading and RDT result over the 28 day follow up was presented and comment expressed on the variation in TF prediction based on initial line intensity of HRP 2 and pan antigen detection.

- Positive HRP 2 and pan malaria antigen results were moderately predictive of TF on each day of follow up with PPV values higher in those with intense initial line HRP 2 and panmalaria antigen line positivity.
- Negative predictive values did not offer predictive advantage over microscopy.

Accuracy of HRP2 and pan-malaria antigens in correctly predicting response to treatment was <95% on each day of follow up.

*Usefulness of paper (rated by reviewers):* 4

* 1. No direct relevance. 2. Very unlikely to influence current practice. 3. Likely to influence current practice in some settings. 4. Likely to influence current practice in many areas. 5. Highly likely to influence current practice in many areas.

**Disclaimer:**

The views expressed in this report are those of the independent reviewers and do not necessarily reflect the views or policies of the World Health Organization.