Summary Table

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<tr>
<td>RDT product(s):</td>
<td>OptiMAL 48 for pLDH from Flow Inc. Portland, OR. No details of the kit contents or user instructions are given</td>
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<td>Target antigens:</td>
<td>OptiMAL: pLDH Pf specific and pan antigen</td>
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<td>Comparative standard(s):</td>
<td>Microscopy</td>
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</table>
| Trial type: Accuracy / Cost-benefits / public health impact / ease of use / behavioral: | Trial is designed to discover if RDT is:  
- Less accurate than available microscopy for a refugee situation  
- Could influence diagnostic choice in emergency situations  
- Effect of cost implication |
| *Usefulness of paper (rated by reviewers):* | 3 |
| Major findings/implications: |  
- Expert reference microscopy was shown to be more sensitive than field microscopy although no parasitaemia value for lower levels are shown which influences interpretation data for RDT.  
- OptiMAL performed less well for diagnosing *P.falciparum* and *P.vivax* than field microscopy (microscopy J value higher for both *P.falciparum* and *P.vivax* compared to RDT)  
- Lower average values for *P.vivax* sensitivity for OptiMAL found although those for *P.falciparum* are in the upper range. Agreement with wide sensitivity variations seen in other studies confirmed  
- Relative cost comparisons show a marked increase in cost for RDT programme compared to microscopy  
- Decisions for recommended usage for emergencies or where microscopy is not available may be required |

**Country:** Pakistan

**Trial type**

The authors are establishing the accuracy, ease of use and cost implications for use of RDT compared to standard microscopic diagnosis of malaria in basic health units for refugees.

The study was conducted using the laboratory staff of the Basic Health Units attached to the Afghan Refugee camps in NWP Pakistan and expert reference microscopy in the HNI laboratory in Peshawar. BHU laboratory staff examined the blood films and performed the RDT. Reference laboratory re-examined all the blood films and the variations were presented.

The immunochromatographic RDT under evaluation  
- OptiMAL 48 for pLDH specific *P.falciparum* and pan antigen detection from Flow Inc. Portland, OR, no lot number or expiry date indicated, no comment on ease of use of RDT was made  
- Storage was not as per manufacturers recommendations but physical conditions are not mentioned.  

Patients presenting to the clinics with clinically suspected malaria were included although no age breakdown is used. RDT was performed on all presenting patients. Thin/thick blood slides were prepared for onsite microscopy after Giemsa staining.
BHU microscopists were given instruction on the use of RDT and examined 100 fields of stained thick film before declaring negative. Blinding of readers for microscopy evaluation was not stated. All smears were cross-checked at the HNI reference laboratory according to protocols used there. Parasitaemia was not counted but a rough estimation was made by microscopists retrospectively. OptiMAL tests were performed following manufacturers instructions exactly at the field site but no reference to background training or competency levels for standardisation of RDT reading is made.

**Results and analysis:**

492 samples were examined by field/reference microscopy and RDT and included in the study. 5 false positive and 167 true positives by microscopy and 7 false positives and 163 true positives by RDT were found. Data was analysed using performance indices of sensitivity and specificity as well as PPV and PNV with the j index (reliability) calculated and compared to results obtained by Giemsa stained blood film microscopy (gold standard). From this data comparative tables of results of microscopy versus OptiMAL and field microscopy versus reference microscopy were prepared although no stratified parasite densities were given for lower value evaluation.

*Usefulness of paper (rated by reviewers): 3*

* 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.