EVALUATION OF OPTIMAL ASSAY TEST TO DETECT IMPORTED MALARIA IN ITALY


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<table>
<thead>
<tr>
<th>RDT product</th>
<th>Optimal, Flow inc. Portland, Or, USA ParaSight F, Becton Dickinson, Cockeysville, Md. USA</th>
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<tbody>
<tr>
<td>Target antigens</td>
<td>pLDH, HRP 2 and pan malaria antigen</td>
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<tr>
<td>Comparative standard (s)</td>
<td>Microscopy and PCR</td>
</tr>
<tr>
<td>Trial type: Accuracy / Cost-benefits/ public health impact /ease of use /behavioural</td>
<td>Laboratory based trial and evaluation of RDT accuracy. No cost comparison, ease of use or possible health impact was noted. Authors considered these RDT may be used where microscopy is limited</td>
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</tbody>
</table>

*Usefulness of paper (rated by reviewers): 2

Major findings/implications

- HRP2 of ParaSight F had greater sensitivity for detection of P falciparum than OptiMAL
- ParaSight F and OptiMAL sensitivity and specificity for P falciparum was as good as microscopy for parasitaemia >0.1%
- Inability of the RDT’s to distinguish mixed infections or parasite densities are limitations

Origin  Italy

Trial type

Laboratory based trial to evaluate OptiMAL RDT in cases of imported malaria in Italy conducted at the Department of Pathology and Laboratory Medicine, University of Parma and Microbiology Laboratory, Arcispedale of Reggio Emilia.

Selected patients attending over a period of 6 years, with a history of malaria like symptoms, fever and travel to an area of malaria endemicity. 139 blood samples were taken from individuals and thick and thin blood films and ParaSight-F RDT were performed immediately on all the samples and an aliquot of blood was stored at 4ºC /-20ºC and subsequently used for testing with the OptiMAL RDT test.

Blood films were examined by an experienced microscopist examining 50-100 fields of a thick film, parasitaemia was determined on all positive slides.

24 control blood samples with positive rheumatoid factor (18), High levels LDH (4), Histoplasma capsulatum infection (1) and Strongyloides infection (1) were also tested. ParaSight-F RDT tests were performed according to the manufacturers’ instruction on the day of arrival to the laboratory.

OptiMAL assays were performed within 4 days and read by 4 examiners blinded to results of the microscopy. No comments were made on kit expiry date, storage, packaging, ease of use or training for use of the RDT prior to testing was noted.

5 samples negative by microscopy but positive by either of the RDT were subjected to PCR investigation.

PCR and southern blot hybridisation were performed according to the method used in the laboratory and hybridisation followed the procedure described by Manca et al. in order to separate Plasmodium species.

Results and analysis:

No statistical program or calculations are shown but the tables shown do give a good overview of the results obtained
Of the 139 blood films were examined microscopically, 56 cases of *P. falciparum* and 10 of non-falciparum were found. 73 cases had no malaria detected.

For *P. falciparum* detection, ParaSight-F sensitivity was 94% and for OptiMAL 83%. ParaSight-F specificity was 95% and OptiMAL was 97%.

OptiMAL also detected 70% of the non-falciparum cases with 6/10 being non-falciparum and 1 was another *P. falciparum*.

5 cases with negative microscopy and positive RDT were shown by PCR to be false positives by RDT.

Sensitivity of both RDT declined below 0.1% parasitaemia but had 96-100% sensitivity above 0.1%. Sensitivity for non-falciparum using OptiMAL varied depending on the species detected and parasitaemia present. Although there is variability in detection at various parasitaemia levels no stage description is given for this group.

There is no discussion on whether the freeze storage of blood could have affected the performance of the OptiMAL test as the other comparative tests were not stored in the same way prior to testing.

**Rheumatoid factor controls:** 2/18 of the Rh factor controls were positive with OptiMAL with no history of malaria exposure.

**Implications**

ParaSight-F was slightly more sensitive but less specific than OptiMAL for *P. falciparum* infections < 0.1% parasitaemia in this study but did not detect non-falciparum cases detected with OptiMAL.

*Usefulness of paper (rated by reviewers):* 2

* 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.

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