Summary Table.

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<table>
<thead>
<tr>
<th>RDT product(s):</th>
<th>Binax NOW® Binax, Portland, Me, USA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target antigens:</td>
<td><em>P falciparum</em> specific HRP 2 and pan-specific Aldolase</td>
</tr>
<tr>
<td>Comparative standard(s):</td>
<td>PCR and microscopy</td>
</tr>
<tr>
<td>Trial type: Accuracy / Cost-benefits/ public health impact /ease of use / behavioral:</td>
<td>Trial is a laboratory based comparison of RDT, PCR and microscopic diagnosis of malaria in returning travellers from malaria endemic areas/possible uses for non endemic areas are discussed</td>
</tr>
</tbody>
</table>

*Usefulness of paper (rated by reviewers):  3

| Major findings/implications: | • Binax NOW® is a sensitive and specific test for *P falciparum* and *P vivax* in febrile returning travellers  
• Binax NOW® is a specific but less sensitive test for other non-falciparum malaria in returning travellers  
• Lack of microscopic diagnostic skills for malaria in laboratories in non-endemic areas can make the Binax NOW RDT a valuable preliminary diagnostic tool |

**Country:** Canada

**Trial type**

A research laboratory based study of the performance of the NOW® ICT test compared with a blinded polymerase chain reaction (PCR) and microscopic analysis for the diagnosis of all human malaria species in febrile travellers returning from malaria endemic areas.

RDT under evaluation is the Binax NOW® (Binax inc (Portland ME), a device that uses monoclonal antibodies to detect both HRP-2 and pan specific Aldolase antigens. The lot numbers or expiry dates of RDT used are not given.

Whole blood samples were collected from all patients presenting to the Tropical Disease unit of the Toronto General Hospital during the study period with fever > 38°C or history of fever within 48hrs and travel to malaria endemic areas.

Thick and thin blood films were prepared and PCR and RDT performed on all samples. A single microscopist blinded to all other results read all the slides, expertise at microscopic examination was stated. Examination of 500 fields of thick films was made before considering negative. Parasite concentration was calculated against 200 or 500 white blood cells and expressed/µL using baseline total WBC. PCR amplification and species identification was performed blinded to other test results. RDT was performed according to manufacturers instructions, independently examined and interpreted by 3 observer blinded to other results. Readings of test lines were graded for intensity.
Results and analysis:

Sensitivity and specificity of the Binax NOW® RDT were calculated with PCR results as reference standard. PPV and NPV were calculated based on malaria prevalence in all patients presenting during the study period. K statistic was used to measure agreement among the 3 observers.

256 individuals were enrolled of which PCR confirmed 101 to be positive for *P. falciparum*, 90 with *P. vivax*, 9 with *P. ovale* and 3 with *P. malariae*. Compared to PCR, Binax NOW® ICT had 2 false positive and 23 false negative results with sensitivity of 95.5% for *P. falciparum* alone, and 94.3% for mixed infection including *P. falciparum*, 86.7% for *P. vivax* and 83.5% for all non falciparum infections. *P. ovale* and *P. malariae* alone had a sensitivity of 61.5%. Based on malaria prevalence of 15% during the study the PPV was 89.8% (*P. falciparum*) and 88.4% (non-*P. falciparum*).

K value for observer agreement was 0.99 (*P. falciparum*) and 0.94 (pan line).

When compared with microscopy Binax NOW® had 19 false negative results, 15 of which had parasitaemia below 1000/µL, and sensitivity of 96% (*P. falciparum*) and 84.7% (non-*P. falciparum*).

No stratified results were used in this evaluation although low parasitaemia and prozone may lead to false negative results for the RDT.

**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.