Summary Table

| Bedside diagnosis of imported malaria using the Binax NOW malaria antigen detection test | LOTHAR WEISE, BRITA BRUUN, LIEF BAEK, ALICE FRIIS-MOLLER, BENTE GAHRN-HANSEN, JOANNA HANSEN, OLE HELTBERG, TOVE HOJBJERG, MAREN KATHERINE HORNSTRUP, BIRGIT KVINESDAL, GRETHE GOMME & JORGEN A.L. KURTZHALS  
  *Scandinavian Journal of Infectious Diseases, 2006; 38: 1063-1068*

| RDT product | Binax NOW ICT Pf/Pv  
Binax Inc. Portland, Maine, USA |
<table>
<thead>
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<tbody>
<tr>
<td>Target antigens</td>
<td>HRP 2 and Aldolase pan sp. antigen</td>
</tr>
<tr>
<td>Comparative standard(s)</td>
<td>Microscopy of thin/thick blood films</td>
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<tr>
<td>Trial type: Accuracy / Cost-benefits / public health impact / ease of use / behavioural</td>
<td>A prospective multi centre QC study of the use of Binax NOW ICT Pf/Pv as a bedside test and as a laboratory based test for malaria, no cost benefit was considered.</td>
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*Usefulness of paper (rated by reviewers): 3*

**Major findings/implications**

- Reliability and sensitivity of bedside Binax NOW testing was not up to laboratory testing standard
- Bedside use of the Binax NOW test alone are not sufficient to guide malaria treatment in a non-endemic country for several reasons stated
- Binax NOW ICT had a good sensitivity for *P falciparum* malaria detection (95% laboratory based) but not for non-falciparum diagnosis (41% laboratory based).

**Origin:** Denmark

**Trial type:**

A prospective multi centre QC study of the use of Binax NOW ICT Pf/PV as a bedside test and as a laboratory based test for malaria with microscopy of thick and thin blood films as the gold standard.

Additionally the study reviewed the mean thrombocyte and serum LDH levels as surrogate markers for malaria infection.

Patients prospectively chosen from those attending Infectious disease units in 7 hospitals in Denmark with fever >38°C and recent travel history to malaria endemic areas presenting between August 2003-October 2004 were included.

The RDT kits were centrally purchased lots and stored and used according to the manufacturer’s instructions. Lot numbers and storage conditions of the DT were documented.

Initial training on the use of the RDT was given and additional update training for RDT use was continually given although no mention of the training materials or standardised interpretation tools to rate the band intensity were made.

An RDT was performed at the patient bedside and thick/thin blood films prepared.

The blood films and venous blood sample were sent to the laboratory where a further Binax NOW ICT test was performed by second person blinded to the result obtained from the bedside. Giemsa stained blood films were examined by an expert reader but no second reading of smears or blinding to the RDT results was noted.

Parasite density was not well recorded and stratification of the parasite level compared to the RDT intensity was not made.

**Results and analysis:**
542 patients from all centres were included, 228 from Africa, 133 from Asia, 24 from Americas and 9 from Pacific area. 148 had no travel history. 376 samples were tested at the bedside and in the laboratory, 45 samples were tested at the bedside only and 121 samples were tested in the laboratory only. 61 were diagnosed as \( P \) falciparum, 11 as \( P \) vivax, 3 as \( P \) malariae, 3 as \( P \) ovale and 2 as Plasmodium sp. by microscopic examination.

No specific analytical system was stated as being used for analysis but sensitivity, specificity and PPV for the use of the Binax NOW were calculated but sensitivity of Binax NOW results against stratified parasitaemia levels were not undertaken.

Binax NOW had a bedside sensitivity of 87.7\% (Specificity 99.7\% and PPV of 99.7\%, NPV 99.7\%) for \( P \) falciparum diagnosis and 94.8\% sensitivity (99.3\% specificity and 99.5\% PPV, NPV 99.5\%) for laboratory diagnosis for \( P \) falciparum.

Both the bedside and laboratory Binax NOW ICT testing had less favourable detection of non-falciparum cases (bedside 6/11 Pv and 1/3 Pm and laboratory 3/8 non falciparum cases).

5 \( P \) falciparum cases detected by microscopy and RDT in the laboratory were missed by bedside RDT testing with 3 negative and 2 invalid tests.

Some technical and practical problems experienced by the bedside testers involved the handling of the capillary tubes and absence of buffer solution from the kit.

Of 3 apparent false positive cases diagnosed in the laboratory, 2 had received treatment within last 2 weeks. One case with parasitaemia of 31\% gave only a weak band.

Additional information was that 77\% of patients with \( P \) falciparum showed low platelet counts compared to 33\% without \( P \) falciparum and 35\% had raised serum LDH levels.

**Implications:**

Usefulness of Binax NOW as a bedside test is limited to areas of non-availability for expert microscopic diagnosis or in situations of infrequent malaria cases but bedside testing using Binax NOW RDT is insufficient for guidance of malaria treatment in non-endemic countries.

*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:**
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