

Comparison Of Three Antigen Detection Tests For Diagnosis And Follow-Up Of Falciparum Malaria In Travellers Returning To Berlin, Germany

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Parasitol Res (2003) 89: 354-357

Products Evaluated

BinaxNow® Malaria - ICT Malaria (Inverness Medical)
ParaSight-F (Becton Dickinson – no longer available)
OptiMal (Flow)

The study was carried out over 3 years at the Department of Infectious Diseases, Charite, Berlin between February 1998 and April 2001. It was a prospective, long term, hospital-based study conducted with specimens collected from patients presenting with acute febrile disease indicative of malaria.

A total of 1073 specimens were tested from 850 patients, of these 231 were infected with *Plasmodium* sp and 619 were negative by microscopy. Not all of the patient specimens were tested in parallel on all tests.

Abstract

We determined the sensitivity and specificity of three rapid immunochromatographic malarial antigen detection test systems (RDTs) for the detection of *Plasmodium falciparum* and assessed the quality of follow-up results. ParaSight-F and ICT Malaria detect histidine-rich protein-2 (HRP-2), whereas OptiMal detects plasmodial lactate dehydrogenase (pLDH). ParaSight-F performed with 95.1% sensitivity and 97.1% specificity (554 patients tested of whom 144 had falciparum malaria). ICT Malaria performed with 95.7% sensitivity and 99.2% specificity (718 patients tested of whom 184 had falciparum malaria). OptiMal performed with 76.2% sensitivity and 99.7% specificity (539 patients tested of whom 130 had falciparum malaria). In follow-up investigations, HRP-2 did not appear to be a useful antigen due to its long half-life, whereas pLDH offers a reasonable correlation with the presence of viable parasites in those cases initially detected. We therefore conclude that a combination of both antigens might be the best option for creating a reliable RDT for the diagnosis of falciparum malaria.

Results and Discussion

<i>P. falciparum</i>	Sensitivity		Specificity	
BinaxNOW® Malaria*	128/131	97.7%	332/336	98.8%
Parasight-F	137/144	95.1%	368/379	97.1%
OptiMal	99/130	76.2%	383/384	99.7%

*Data for BinaxNOW P.f/P.v test only, data for the BinaxNOW Pf test has been excluded.

BinaxNow® Malaria and ParaSight-F both detect HRP-2 and the OptiMal test detects the pLDH. Based on the data from the trial HRP-2 is more efficient in detecting a *P. falciparum* infection than pLDH. **Note:** The Parasight-F test has now been withdrawn from the market and is no longer available.

The paper shows that tests based on the detection of the HRP-2 antigen are a valuable diagnostic tool where expert microscopy is not available.

However the clinical performance of the OptiMal test makes it unsatisfactory for the diagnosis of falciparum malaria. BinaxNow® Malaria has been shown to have good clinical performance and is better than OptiMal for the detection of falciparum malaria.