

A-23: Field evaluation of an antigen detection dip-stick test (ParaSight™-F test) for the diagnosis of *Plasmodium falciparum* malaria.

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The Dip-stick test, "ParaSight™-F" is a rapid technique for the diagnosis of falciparum malaria, developed by Becton-Dickinson Inc. The test is based on

the qualitative detection of *P.falciparum* blood stage antigen, the histidine rich protein-2 (PfHRP-2), which is released into blood by the developing parasite. This study was carried out to assess the sensitivity and specificity of the antigen detection dip-stick method for the field diagnosis of *P.falciparum* malaria infections, using the thick and thin blood smear microscopic examination as the standard, under routine field conditions.

The study was performed in the Kurunegala District and data was collected at mobile field clinics, where patients from this malaria endemic area routinely attended for diagnosis and treatment of malaria. A few samples were collected during mass blood surveys.

In this evaluation, the "ParaSight™-F" test was compared to the standard thick and thin blood film microscopical examination. Each of the 2 tests were carried out simultaneously, but independently. A microscopist from the Anti-Malaria Campaign examined blood films, and the Dip-Stick test was performed elsewhere by the investigator.

A blood film and sample of blood were collected into a capillary tube from each patient from finger prick blood. The Giemsa-stained thick blood film was examined by screening 100 microscopic fields as usual. The Dip-stick was performed according to directions given in the test kit.

The discrepant samples were re-checked as follows: When a blood film was negative for *P.falciparum* and Dip-Stick positive, it was re-examined by the same microscopist to cover more than 400 fields, and if it was still negative another fresh blood film was examined by a second microscopist.

When a blood film was positive for *P.falciparum* and it was Dip-Stick negative, the dipstick test was recreated, and in the meantime the stage of the parasite and the parasite count was estimated by microscopy.

A total of 904 samples of blood were examined by both methods. The sensitivity and specificity of the "ParaSight™-F" test were 89.9% and 97.9% respectively, taking the microscopic examination in 100 microscopic fields as the standard.

After re-examination of discrepant samples, the sensitivity and specificity of the "ParaSight™-F" test increased up to 96.8% and 98.5% respectively.

Comparison of operational feasibility of dip-stick method & microscopy

Criterion	Thick blood film	Dip-stick
1. Time taken for test:		
a. On a busy day at field clinic	75 min	25-30 min
b. In Laboratory	30 min	08-10 min
2. Sample collection from small children	fairly difficult	more difficult
3. Field application	fairly easy	easier
4. Time required for staff training	3 months (at least)	1 day
5. Detection of Gametocyte	possible	difficult/impossible
6. Estimation of Parasitaemia	possible	impossible
7. Species Identification	all species	only <i>P. falciparum</i>

This new Dip-stick method, the "ParaSight™-F" is likely to be useful in malaria endemic situations for the diagnosis of *P. falciparum* patients for treatment, and in epidemiological studies. This is based on the high degree of sensitivity and specificity of this method compared to the conventional method of microscopic diagnosis and its simplicity and speed of operation in a field situation.

The test however, is unlikely to detect *P. falciparum* infections with only gametocyte states, as can occur in chronic chloroquine-resistant infections. The availability of a *P. vivax* diagnostic assay on the same Dip-stick, and economic considerations, would determine whether this method could substitute for, and even replace microscopy in the routine diagnosis of malaria in Sri Lanka.

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