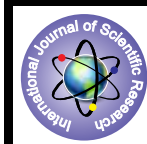


## Evaluation of Immunochromatographic Antigen Detection Assay As A Rapid Diagnostic Tool for Malaria Against Standard Microscopy



### Medical Science

**KEYWORDS :** Immunochromatography, Plasmodium, Malaria

<b>Dr. Bharti Parghi</b>	Government Medical College, SIR T. Hospital Bhavnagar, Gujarat, India.
<b>Dr. Nidhi Vora</b>	Government Medical College, SIR T. Hospital Bhavnagar, Gujarat, India.
<b>Dr. Paresh Shiladariya</b>	Government Medical College, SIR T. Hospital Bhavnagar, Gujarat, India.
<b>Dr. Gautam Chauhan</b>	Government Medical College, SIR T. Hospital Bhavnagar, Gujarat, India.

### ABSTRACT

Study was conducted to evaluate performance of rapid diagnostic tests, an Immunochromatographic antigen detection assay for diagnosis of malaria using parasite lactate dehydrogenase antigen (pLDH Ag) against standard microscopy of Giemsa stained thick blood film and Field's stained thin blood film. A total 350 patients with suspected malaria, coming to Sir T. Hospital, taken as a study sample. Thin blood film & Thick smears were made & examine for malaria parasite by light microscopy & whole blood samples were tested with Immunochromatographic antigen detection assay. Out of which 146(41.7%) were positive by blood film while 137(39.1%) were positive by Immunochromatographic antigen detection assay test. Blood film shows 108 (73.9%) were positive for Plasmodium Vivax and 38 (26.1%) were positive for plasmodium Falciparum. Immunochromatographic antigen detection assay test shows 103 (75.2%) were positive for Plasmodium vivax and 34(24.8%) were positive for Plasmodium Falciparum with sensitivities of 95.3% and 84.2% compared to traditional blood film for detection of plasmodium Vivax & Falciparum. Rapid diagnostic test proved to be valuable adjuvant to clinical and blood film microscopy.

**Introduction :** Malaria is caused by intracellular parasite plasmodium, a worldwide infestation that affect 500 millions and kills more than 1 million people each year,<sup>(1)</sup> So a prompt and accurate diagnosis is the key to effective disease management.<sup>(2)</sup> Conventional light microscopy has been the established method for malaria diagnosis and identification of species by morphology. However number of screening tests based on immunological method has been developed for the detection of malarial antigen.<sup>(3)</sup> This assay can be used for the diagnosis of malaria in the area where the microscopy is not available and urgent malaria diagnosis at night or weekend can be done by relatively inexperienced microscopist<sup>(4)</sup>

**Material and method:** The study included 350 patients referred to us for investigation of malaria by different clinicians of Sir T. general hospital, Bhavnagar from the period of June 2012 to December 2012. This study was approved by the Institutional Review board, Government Medical College, Bhavnagar. From each patient venous blood collected in to sterile vacutainer containing EDTA. Thin and thick smear blood films were made from received samples, stained with Giemsa stain & then examined for malaria parasite (MP) by light microscopy according to standard practice (thin blood smear was examined for 15 minutes and for a thick blood film 200 fields were visualized). All the slides were examined independently by two pathologists & when there was difference of opinion a third pathologist's opinion was taken into account. All whole blood samples were tested with the immunochromatographic antigen detection assay test (parasite lactate dehydrogenase based Immunochromatographic antigen detection assay) according to manufacturer's instructions. Interpretation of the assay test strip results was done as below:

- **Negative Reaction:** The presence of only one band within the result window indicates negative results.
- **P. Vivax:** The presence of two colour bands one control band & one test band, the test was considered positive for P. Vivax.
- **P. Falciparum:** The presence of three colour bands, one control band & two test bands, the test was considered to be positive for P. Falciparum
- **Invalid Test:** The test is invalid if the control band not appears, if this occurs the test should be repeated using new strip.

### Results:

A total 350 blood samples were tested for malarial parasites by Immunochromatographic antigen detection assay test & results were compared to those obtained from examination of thin &

thick smear blood films. The blood film results were positive in 146 (41.7%) patients & rest 204 (58.2%) patients were malaria negative. Among the positive patients, P.Vivax was detected in 108 (73.98%) cases and P. Falciparum in 38 (26.02%) cases. Correspondingly Immuno-chromatographic antigen detection assay test detect 137 (39.1%) as malaria positive & 213 (60.8%) as malaria negative. Among the positive P. Vivax was detected in 103 (75.1%) cases & P. Falciparum in 34 (24.8%) cases. [Table I]

**Table I Comparison of Immunochromatographic Antigen Detection Assay Test With Peripheral Blood Smear Examination for Malaria Parasite Detection**

Name of species	Rapid test result	Blood Film result		
		Positive	Negative	Total
P.Vivax	Positive	103	00	103
	Negative	05	242	247
	Total	108	242	350
P.Falciparum	Positive	32	02	34
	Negative	06	310	316
	Total	38	312	350

### Discussion:

In our study antigen detection test identified 39.1% as malaria positive while blood film identified 41.7% as malaria positive which is comparable with Jamshid Iqbal et al show 42 % malaria positive by pLDH antigen detection test<sup>(2)</sup> and Grobusch et al showing 24 % malaria positive by pLDH antigen detection test.<sup>(5)</sup> MP Positive in Peripheral smear get MP negative in card test because of misuse of anti-malarial drugs in inadequate doses for any fever. Since Immunochromatographic antigen detection assay test detects pLDH which is produced by living parasite, the blood samples judged negative by Immuno-chromatographic antigen detection assay test may have been dead parasite & not yet cleared from the host.<sup>(6)</sup> Five cases of P.Vivax & six cases of P. Falciparum detected by blood film were not detected by Immunochromatographic antigen detection assay test. This may be due to insufficient enzyme production which occurs during early malarial infection or patient's blood sample contained parasite at the concentration below the Immunochromatographic antigen detection assay test's detection level.<sup>(7)</sup>

Two cases blood sample in which Immunochromatographic antigen detection assay test detects P.Falciparum band were found

to be negative in blood smear examination, may be due to the fact that *P. Falciparum* can sometime sequester & may not be present in a circulating blood.<sup>(9)</sup> The blood films examination identified 5 cases of *P.Vivax* sample that were not detected by Immunochromatographic antigen detection assay test, However there was 100% agreement between peripheral smear & Immunochromatographic antigen detection assay test results for the 103 samples containing *P.Vivax*. Two cases of *P.Falciparum* detected by card tests were not detected by blood film & 6 cases of *P.Falciparum* detected by blood film were not detected by card test.

In our study the sensitivity of Immunochromatographic antigen detection assay test for *P.Vivax* is 95.3% & for *P.Falciparum* it is 84.2%, which is comparable to palmer CL et al having sensitivity of Immunochromatographic antigen detection assay test for *P.Vivax* is 94% & for *P.Falciparum* it is 88 %.<sup>(8)</sup>

Jamshid Iqbal et al study show sensitivity of Immuno-chroma-

tographic antigen detection assay test for *P.Vivax* 79 % and *P. Falciparum* 87 %.<sup>(2)</sup>

#### CONCLUSION:

Rapid diagnostic test based on plasmodium antigen detection may develop into important diagnostic tool & can prove to be a valuable adjuvant to clinical & blood film microscopy, however selection of quality manufactured malaria rapid diagnostic test kit (MRDT) based on product stability, sensitivity and specificity for detection of each of those species, specially in region with high incidences of relapsing malaria because these infection would warrant initial selection of additional drugs for treatment. The parasitemic or antigenemic concentration threshold at which the test is able to identify it's target (lower limit of detection) should also considered. Still this test has lower capital cost and infrastructure, lower maintenance cost, less training required and rapid diagnostic test in remote area. Moreover the test is simple to perform & interpret, however they should not yet be regarded as a first line diagnostic test.

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