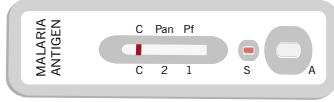
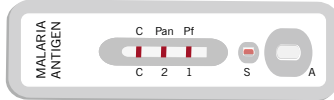


INTERPRETATION OF RESULTS

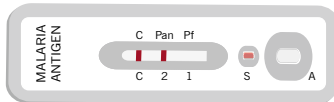
NEGATIVE for Malaria: If coloured band appears at the control region 'C' only.



POSITIVE for *P. falciparum* or mixed infection: In addition to the control band, two pink-purple bands appear at regions 'Pf' and 'Pan' in the test window.

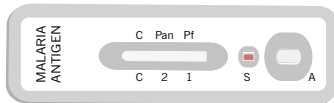


POSITIVE for Pan (other species *P. vivax* / *P. ovale* / *P. malariae*) : In addition to the control band, one pink-purple band appears only at region 'Pan' in the test window

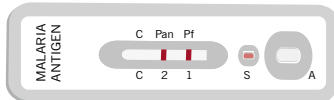


INVALID: The test should be considered invalid if,

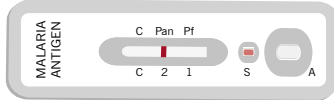
A) No line appears at 'C', 'Pf' and 'Pan' regions.



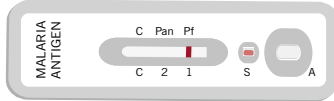
B) No line appears at 'C' region and line appear at 'Pf' and 'Pan' region



C) No line appears at 'C' and 'Pf' region and line appear at 'Pan' region



D) No line appears at 'C' and 'Pan' region and line appear at 'Pf' region



PERFORMANCE CHARACTERISTICS: -

Internal Evaluation:

In an in-house study, total 225 samples were evaluated for sensitivity and specificity. We found the relative sensitivity was 100 % (i. e. 115/115) and the relative specificity was 100 % (i. e. 110/110). The results are summarized in the following table:

Sample	Total Number of samples tested	Rapid Malaria Pf (HRP 2) / Pan (pLDH) Antigen Test		Sensitivity (%)	Specificity (%)
		Positive	Negative		
Pfalciparum Positive	55	55	0	100	-
Pan Positive	60	60	0	100	-
Malaria Negative	110	0	110	-	100

LIMITATIONS

- As with all diagnostic tests, the test result must always be correlated with clinical findings.
- The results of test are to be interpreted within the epidemiological, clinical and therapeutic context. When it seems indicated, the parasitological techniques of reference should be considered (microscopic examination of the thick smear and thin blood films).
- Any modification to the above procedure and / or use of other reagents will invalidate the test procedure.
- The test is limited to the detection of antigen to Malaria Plasmodium sp. Although the test is very accurate in detecting pLDH and HRP-2, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
- In case of mixed infection (P.falciparum, with other malarial species), both, 'PF' and 'pan'malaria bands will be positive. Hence, differentiation of infection due to P. vivax, P. ovale or P.malariae cannot be done.
- Usually the 'Pan' band turns negative after successful anti malaria therapy. However, since treatment duration and medication used affect the clearance of parasites, the test should be repeated after 5-10 days of start of treatment.
- In P.falciparum malaria infection-2 is not secreted in gametogamy stage. Hence, in "Carriers", the HRP-2 band may be absent.
- HRP-2 levels, post treatment persists upto 15 days, the 'Pan' band can be used to monitor success of therapy in P.falciparum malaria cases.
- In few cases, where the HRP-2 band is positive and the 'Pan' malaria band is negative, it may indicate a case of post treatment malaria. However, such a reaction pattern may also be obtained in a few cases of untreated malaria. Retesting after 2 days is advised, in such cases. Do not interpret the test results beyond 30 minutes

REFERENCES

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- Quintana M., et. al., (1998) Malaria diagnosis by dipstick assay in a Honduran Population with coendemic Plasmodium falciparum and Plasmodium vivax. Am. J. Trop. Med. Hyg. 59(6) 868-871
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- John, S. M., et. al., (1998) Evaluation of OptiMAL , a dipstick test for the diagnosis of malaria. Ann. Trop. Med. Parasitol., 92, 621-622.

SYMBOL KEY

IVD	In Vitro Diagnostic Use		Temperature limitation
	Manufacturer		Single Use Only
	Manufacturing Date		Number of tests in the pack
	Expiry Date		Do not use if pouch or kit damaged
LOT	Lot Number		Read package insert before use