First Romanian rapid tests manufacturer !

rev1

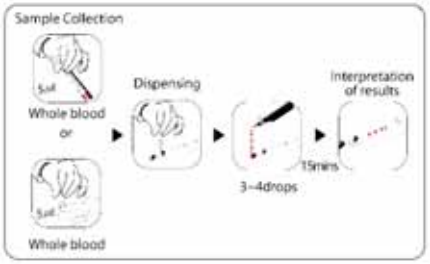
e-mail : sales@campmedica.ro
http:// www.campmedica.ro

"See Now" Malaria P.f / Pan Antigen Cassette Test -Whole blood

CE

For in vitro Diagnosis Use

Product Code: SN 8.1



INTRODUCTION

The *"See Now"* Malaria P. f / Pan Test is a rapid and convenient immunochromatographic in vitro assay. It is a designed for detection of P. falciparum (HRPI) and pLDH (P. falciparum, P. vivax, P. ovale, P. malariae) in human blood.

SUMMARY OF THE TEST

Malaria is one of the worldwide diseases known as a mosquito-borne infectious disease. It is accompanied by the symptom such as high lever, shivering, arthralgia (join pain), vomiting and etc. The typical symptom of malaria is cyclical occurrence of sudden coldness followed by rigor and lever and sweating. The seriousness depends on the type and the most serious form is caused by Plasmodium falciparum which needs the fast treatment, otherwise it may be fatal to death. Four species of the Plasmodium parasites are responsible for malaria infections in human viz. P falciparum, P vivax, P.ovale and P.malariae.

In humans, the parasites (called sporozoites) migrate to the liver where they mature and release another form, the merozoites. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and maybe 2 million malaria-caused deaths per year.

The *"See Now"* Malaria P. f / Pan Antigen Test is a immunochromatographic assay. As the test sample flows through the membrane assembly, after addition of the cleaning buffer, the colored colloidal gold conjugates of monoclonal anti P. falciparum (HRPI specific) and monoclonal anti Pan (pLDH specific) complexes the HRPI/ corresponding pLDH in the lysed sample. This complex moves further on the membrane to the test region where it is immobilised by the momoclonal anti HRPI and monoclonal anti pLDH specific antibody coated on the membrane leading to formation of pink-purple coloured band, which confirms a positive test result. Absence of coloured bands in the test region indicates a negative test result.

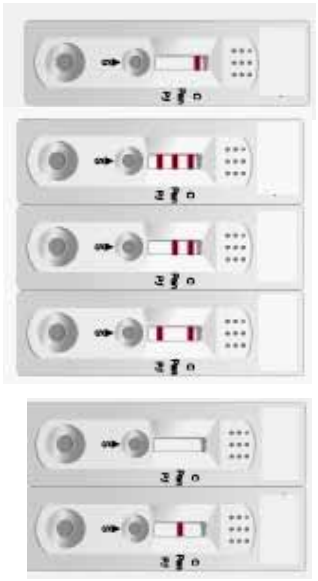
SPECIMEN COLLECTIONAND STORAGE

- Whole Blood specimen
  Use the tube with EDTA or heparin anticoagulant. Gathered blood from syringe can cause faster hemolytic, and should be avoided
  Operate the test within an hour after collecting.
- Finger puncture whole blood
  Clean the finger with an alcohol pad and let dry
  Take a lancet and make a quick deep slab on the side of the finger.
  Avoid squeezing the fingertip to accelerate bleeding as this tends to dilute the blood with excess tissue fluid.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test .Label the test device with patient or control identification
- Remove the test device from the sealed pouch by tearing at the notch. Then place the testing device on a level surface
- Take 5µL of whole blood by loop and drop the specimen in specimen insertion hole,
- Add 3-4 drop of buffer (approximately 120µ) and start the time
- Read the results at 15-30 minutes. Ensure that the background of the test area is white before interpreting the result.Do not read the result after 30 minutes.

INTERPRETATION OF RESULTS



Negative
Only one color band appears at the control region.

Positive
Positive for P. f: two colored band are visible in the test1 regionT1
and control region C
Positive for Pan: two colored band are visible in the test1 regionT2 and control region C
Positive for P. f and Pan: Three colored band are visible in the test 1region T1 and test 2 region T2, control region C.

Invalid
No visible band at the control region. Repeat with a new test kit. If test still fails, please contact the distributor with the lot number.

STORAGE AND STABILITY

The test kit can be stored at temperature (2 to 30°C) in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat.

PRECAUTION

- *FOR IN VITRO DIAGNOSTIC USE ONLY.*
- Don't use it after the expiration date.
- The test device should not be reused.
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PERFORMANCE CHARACTERISTICS

Sample			*"See Now"* Malaria P.f /Pan Antigen Test	
			Positive	Negative
Positive	P. falciparum	50	50	0
	P. vivax	150	149	1
	Total	200	199	1
Negative		200	1	199
Sensitivity			99.5%/199/200	
Specificity			99.5%/199/200	