Malaria P.f/P.v Home Use Rapid Test Kit

(Blood)

Catalog No. WF1102F

Intend Use

iCARE Malaria P.f/P.v Home Use Rapid Test Kit (Blood) is a rapid self-performing, qualitative, two site sandwich immunoassay, utilizing whole blood for the detection of P.falciparum specific histidine rich protein-2 (P.f HRP-2) and P.vivax specific pLDH. The test may also be used for specific detection and differentiation of P.falciparum and P.vivax malaria in whole blood samples and for follow up of anti-malarial therapy. *For in vitro diagnostic use only. For healthcare professional use and Field Use Only.*

Summary

Malaria remains one of the most serious tropical and subtropical diseases in many countries of the world. It is rampant in most areas of the tropics. Malaria is caused by a parasite that is transmitted from one person to person by the bite of infected Anopheles mosquitoes. There are four kinds of malaria that can infect humans: Plasmodium falciparum, P.vivax, P.ovale and P.malariae. Malaria has been reported from blood transfusions or congenitally from mother to child. It is estimated to affect more than 500 million people causing between one and three million deaths per year.

Principle

iCARE Malaria P.f/P.v Home Use Rapid Test Kit (Blood) utilizes the principle of immunochoromatograhpy. As the test sample flows through the membrane assembly of the device after addition of the buffer, the colored monoclonal P.f specific HRP-2, P.v specific pLDH colloidal gold conjugate antibodies complex the proteins in the lysed sample. This complex moves further on the membrane to the test region where it is immobilized by the P.f specific HRP-2 antibody / P.v specific pLDH coated on the membrane.

This leads to the formation of a colored band in the respective regions which confirms a positive test result. Absence of a colored band in the appropriate test region indicates a negative test result for the corresponding antigen.

The unreacted conjugate along with the rabbit globulin colloidal gold conjugate and unbound complex if any, move further on the membrane and are subsequently immobilized by anti-rabbit antibodies coated on the membrane at the control region, forming a pink/purple band. This control band serves to validate the test performance.

Precautions and Warnings

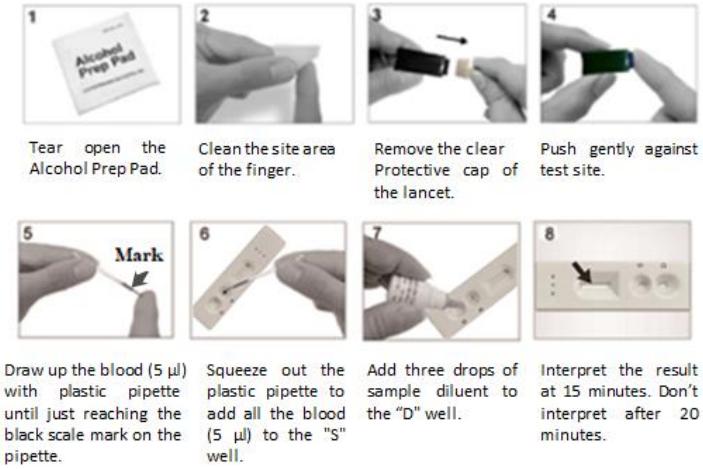
1.This kit is for in vitro use only. Do not swallow.
2.Discard after first use. The test cannot be used more than once.
3.Do not use test kit beyond the expiration date.
4.Do not use the kit if the pouch is punctured or not well sealed.
5.Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
6.Wear protective gloves while handling specimens. Wash hands thoroughly afterwards. Avoid splashing or aerosol formation. Clean up spills thoroughly using an appropriate disinfectant.
7.Keep out of the reach of children.
8.DISPOSAL OF THE DIAGNOSTIC: The used device has the infectious risk. The process of disposing the diagnostic must follow.

Each Kit Contains:

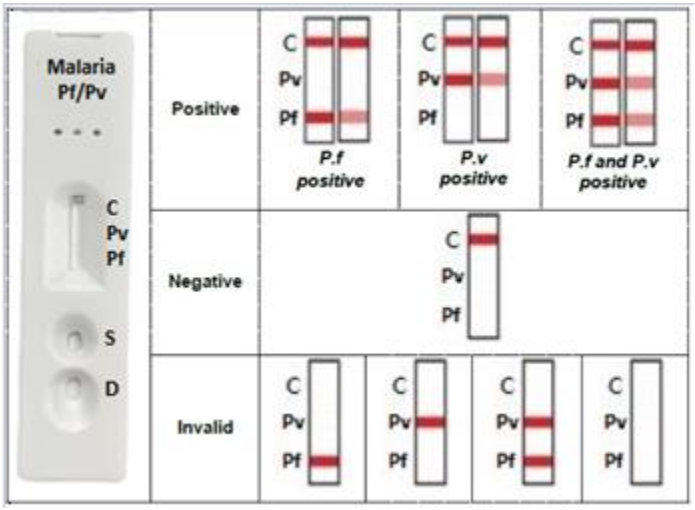
- Test cards individually foil pouched with a desiccant
- Plastic sample dropper(5µl)
- Sample diluent
- Safety lancet
- Alcohol swab
- Package insert

Test Procedure

1.Bring the Malaria P.f/P.v Field Use rapid test card, sample diluent, alcohol swab, safety lancet, plastic dropper to room temperature.
2.Take out the test card from the sealed pouch.
3.To perform the test, please follow the steps closely as follow (from picture 1 to picture 8).



Reading The Test Results



Note:

1.When performing the test, the steps must be followed closely.

2.Use within 10 minutes after opening.

3.Do not share or reuse the lancet.

Storage and Stability

1.Stored at 2~30°C in the sealed foil pouch up to the expiration date.

2.Keep away from sunlight, moisture, and heat. DO NOT FREEZE.

Quality Control

Though there is an internal procedural control line in the test device of Control Region, the external controls are strongly recommended as good laboratory testing practice to confirm the procedure and to verify proper test performance. When testing the positive and negative controls, the same assay procedure should be adopted.

Performance Characteristics

iCARE Malaria P.f/P.v Home Use Rapid Test Kit (Blood) has a sensitivity of >90% at densities above 40~100 parasites /µl blood.

A. Sensitivity and Specificity

Methods	P.v		P.f	
	Positive	Negative	Positive	Negative
Microscopy	390	880	420	920
iCARE Malaria P.f/P.v Field Use Rapid Test Kit (Blood)	388	878	419	919

P.v Performance:

Sensitivity (Positive Percent Agreement): 99.48% = 388/390 (95% CI: 98.15%~99.86%)

Specificity (Negative Percent Agreement): 99.77% = 878/880 (95% CI: 98.18%~99.94%)

Accuracy: 99.68% = (388+878)/1270 (95% CI:99.19%~99.88%)

P.f Performance:

Sensitivity (Positive Percent Agreement): 99.76% = 419/420 (95% CI: 98.66%~99.96%)

Specificity (Negative Percent Agreement): 99.89% = 919/920 (95% CI: 99.39%~99.98%)

Accuracy: 99.85% = (419+919)/1340 (95% CI: 99.46%~99.96%)

B. Precision

1.Within run precision was determined by using 10 replicates of four different specimens containing different concentrations of antigen. The negative and positive values were correctly identified 100% of the time.

2.Between runs precision was determined by using the four different specimens containing different concentrations of antigen in 3 different lots of test devices. The negative and positive results were correctly identified in each test.

Bibliography

1.David R. and et. Al. A Longitudinal Study of Type-Specific Antibody Responses to Plasmodium falciparum Merozoite Surface Protein – 1 in an Area of Unstable Malaria in Sudan, Journal of Immunology, 161: 347-359 (1998).

2.Helen L. Gibson, Jeffrey E. Tucker: Structure and expression of the gene for Pv 200, a major blood-stage surface antigen of Plasmodium vivax. Molecular and Biochemical Parasitology, 50 (1992) 325-334.

3.Alon Warburg and Imogene Schneider. In Vitro Culture of the Mosquito Stages of Plasmodium falciparum. Experimental parasitology 76, 121-126 (1993).

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