YE00411907A

Malaria pf&pv combo test kit （Whole Blood）

INTRODUCTION

Malaria is a disease serious parasitic characterized by fever, chills, and anemia and is caused by a parasite that is transmitte. This Malaria pf&pv test cassette is very sensitive and only takes about 15 minutes. Test results can be read visually without any instruments.

This test is for in-vitro diagnostic use only.

SUMMARY

Malaria is a serious parasitic disease characterized by fever, chills, and anemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. Thereare four kinds of malaria that can infect humans: Plasmodium 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 inmore than 90 countries worldwide, and it is estimated that there areover 500 million clinical cases and 2.7 million malaria-caused deathsper year. At the present, malaria is diagnosed by looking for theparasites in a drop of blood. Blood will be put onto a microscope slideand stained so that the parasites will be visible under a microscope.The Malaria pf/pv Test contains amembrane strip, which is pre-coated with two monoclonal antibodiesas two separate lines across a test strip. One monoclonal antibody(test line 1) is specific to the P. falciparum histidine rich protein-2 (Pf HRP-2) and another monoclonal antibody (test line 2) is specific to the lactate dehydrogenase of the P. vivax species (pvLDH). Conjugatepad is dispensed with monoclonal antibodies conjugated to colloidalgold, which are specific to P. falciparum histidine rich protein-2 (PfHRP-2) and specific to the lactate dehydrogenase of P. vivax.Therefore, the antigen of Plasmodium falciparum and Plasmodiumvivax can be differentially detected.

SPECIMEN COLLECTION

1. Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
2. If specimens are not immediately tested, they should be refrigerated at 2~8℃.
3. Freezing is recommended if the storage periods are more than 3 days.
4. They should be brought to room temperature before testing. Using the specimen after long-term
5. storage of more than three days can cause non-specific reaction

STORAGE ANDSTABILITY

1. The test kit can be stored at temperature 2℃ to 30℃
2. Keep the temperature at 15-30℃ during the test.
3. Keep away from sunlight, moisture and heat.
4. In the sealed pouch to the date of expiration.
5. Patient samples perform best if tested immediately after collection.

MATERIAL

Material provided

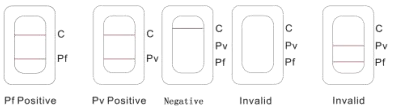
1. 30 Individual sealed pouches, each containing:
   - Test device
   - Desiccant pouch
2. 30 Extraction tubes.
3. One extraction buffer in a dropper bottle (6mL): 0.01M phosphate buffer saline (PBS).

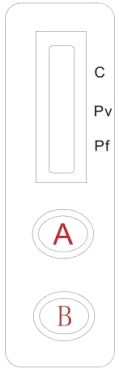
Material Required But Not Provided

- Timer

TEST PROCEDURE

1. Tear the aluminum foil bag along the incision, take out the test card and place it horizontally.
2. Drop the Whole blood sample（2μl） to the scale using A pipette or supplied straw and drop the sample into the filling hole (A).
3. Add 3 drops (approx 120ul) of sample diluent to test card diluent hole (B)
4. Read results after15 minutes. Do not read results after 30minutes.





INTERPRETATION OF RESULTS

Negative: Only one colored band appears on the control (C) region. No apparent indicating no infection

Pv positive: In addition to a pink colored control (C) band, one distinct pink colored bands will also appear in the test (pv) region.This indicates the possibility of pv infection with malaria Please consult your physician to perform a much more detailed exam.

Pf positive: In addition to a pink colored control (C) band, one distinct pink colored bands will also appear in the test (pf) region.This indicates the possibility of pf infection with malaria Please consult your physician to perform a much more detailed exam

Pf&pv positive: In addition to a pink colored control (C) band, two pink colored bands will also appear in the test pv and pf region.This indicates the possibility of pv and pf infection with malaria

Invalid: if the control line does not appear in the test bar, the test result is invalid regardless of whether there are other visible lines in the test bar. Retest with a new reagent cassette.

LIMITATIONS OF PROCEDURE

1. The test procedure, precautions and interpretation of results for this test must be followed when testing.
2. Anti-coagulants such as heparin, EDTA, and citrate do not affect the test result.
3. This test kit detects Plasmodium HRP-2 and lactale dehydrogenase in patient whole blood and is useful as a screening procedure of malaria diagnosis.
4. Do not mix reagent of different lots.
5. The test is limited to the detection of antigen to Malaria Plasmodium sp. Although the test is very accurate in detecting HRP-2 and pvLDH, 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.

REFERENCE

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3.David J. Bzik, Barbara A, Fox and Kenneth Gonyer : Expression of Plasmodium falciparum lactate dehydrogenase in Escherichia coli Motecular and Biochemical Parasitology, 59(1993) 155-166

4. Cameron R. Dunn, Mark J. Banfield, John J. Barker, Christopher W. Highm, Kathleen M. Moreton Dilek Torgut-Balk, R. Leo Brady and J. John Holbrook. The Structure of lactate dehydrogenase from Plasmodium falciparum reveals a new target fro anti-malarial design. Nature Structural Biology 3(11)1996, 912-915

5. Howard, RJ, et al. The secretion of a Malaria Hislidine-rich Protein (Pf HRP II) from Plasmodium falciparum-infected Erythrocyles. J. Cell Biol., (1986)103, 1269-1277

6. Rock, EP, et al. Comparative Analysis of the Plasmodium falciparum Histidine-Rich Proteins HRP-I, HRP-II, and HRP-III in Malaria Parasites of Diverse Origin. Parasitol., (1987) 95:209-227

7.Parra, ME, et al, Identification of Plasmodium falciparum Histidine- Rich Protein 2 in the plasma of Humans with Malaria. J. Clin. Microbiol., (1991) 29:1629-1634

8.Rodriguez-del Valle, M., et al, Detection of Anligens and Antibodies in the Urine of Humans with Plasmodium falciparum Malaria. J. Clin. Microbiol., (1991) 29:1236-1242

INDEX OF SYMBOLS

	See instruction for use		Tests per kit		Manufacturing
	For *in vitro* diagnostic use only		Expiry date		Do not reuse
	Store between 2 ~ 30 ℃		Batch number		Catalog #
	Keep away from sunlight		Keep dry		Authorized Representative

our company is certified by ISO quality system