Malaria Pf/Pv Rapid Test Cassette (Whole Blood)

IVD For *in vitro* diagnostic and professional use only

Store at 2-30 °C CE

INTENDED USE

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of two kinds of circulating plasmodium falciparum(P. falciparum (P.f.) and P. vivax (P.v.)) in whole blood.

INTRODUCTION

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. There are 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 in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. At the present, malaria is diagnosed by looking for the parasites in a drop of blood. Blood will be put onto a microscope slide and stained so that the parasites will be visible under a microscope.

PRINCIPLE

The Malaria P.f. /P.v. Rapid Test Cassette(Whole Blood) is a qualitative, membrane based immunoassay for the detection of P.f. andP.v. antigens in whole blood. The membrane is pre-coated with anti-HRP-II antibodies and anti-pLDH antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test cassette. The mixture then migrates upward on the membrane by capillary action, reacts with anti-Histidine-Rich Protein II (HRP-II) antibodies on the membrane on P.f. Test Line region and with anti-pLDH antibodies on the membrane on P.v. Line region. If the specimen contains HRP-II or Plasmodium-specific P. vivaxLDH or both, a colored line will appear in P.f. line region or P.v. line region or two colored lines will appear in P.f. line region and P.v. line region. The absence of the colored lines in P.f. line region or P.v. line region indicates that the specimen does not contain HRP-II and/or Plasmodium-specific P. vivaxLDH. To serve as a procedure control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test device.
- Buffer.
- Straw
- Package insert.

MATERIALS NOT PROVIDED

- Timer
- Specimen collection containers.
- Pipette
- Lancets (For finger stick whole blood)
- Centrifuge

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C).The test device is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not FREEZE**.
- Do not use beyond expiration date.

PRECAUTION AND WARNINGS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- For whole blood specimen use only. Do not use other specimens.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Follow standard biosafety guidelines for handling and disposal of potential infective material.
- Humidity and temperature can adversely affect results.
- Do not exchange or mix buffer and test cassettes from kits of different lot numbers.
- Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.

COLLECTION, HANDLING AND PREPARATION OF SPECIMEN

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) can be performed using whole blood. Both lancet Whole Blood and Venipuncture Whole Blood can be used.

Collection by venipuncture

- Collect whole blood into a collection tube (containing EDTA, citrate or heparin) by venipuncture.
- If specimens are not immediately tested, they should be refrigerated at 2 - 8°C if the test is to be run within 2 days of collection. For longer storage periods, freezing is recommended. They should be brought to room temperature prior to use. Specimens should not be frozen and thawed repeatedly for more than three times.
- If specimens are to be shipped, they should be packed in compliance with federal regulations covering the transportation of etiologic agents.

Collection using a lancet

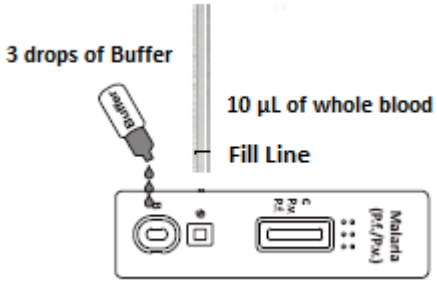
- Clean the area to be lanced with an alcohol swab.
- Squeeze the end of the fingertip and pierce with a sterile lancet provided.
- Wipe away the first drop of blood with sterile gauze or cotton.
- Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.

Whole blood collected by lancet should be tested immediately.

PROCEDURE

Allow test, specimens, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it as soon as possible.
2. Place the cassette on a clean and level surface.
3. Use the provided straw to transfer **10 µL of whole blood** to the specimen well, then add **3 drops** of buffer (approximately **180 µL**) and start the timer.
3. Wait for the colored line(s) to appear. Read results at **10** minutes. Do not interpret the result after **20 minutes**.



INTERPRETATION OF RESULTS (Please refer to the illustration below)

Positive: Two or Three distinct colored lines appear.

P. falciparum or mixed malaria infection: One line appears in the control region, ne line appears in P.v. line region and one line appears in P.f. line region.

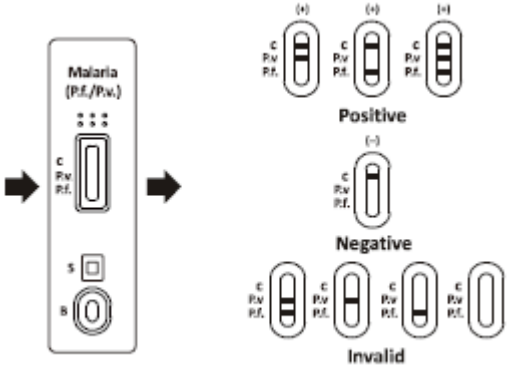
P.falciparum infection: One line appears in the control region, and one line appears in P.f .line region.

Non-falciparum Plasmodium species infection: One line appears in the control region and one line appears in P.v. line region.

NOTE: The color intensity of P.f. or P.v. test lines may vary depending on the concentration of antigens, viz., HRP-II or P. vivaxLDH present in the specimen.

Negative: Only one colored line appears in the control region.

Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



REFERENCE VALUES

The Malaria P.f./P.vRapid Test Cassette (Whole Blood) has been compared with traditional thick and thin blood films microscopic analysis. The correlation between the two systems is over 99.0%.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS AND INTERFERENCES

- Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is for in vitro diagnostic use only. This test should be used for the detection of P.f. and P.v antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f. and P.v., concentration can be determined by this qualitative test.
- Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) will only indicate the presence of antigens of Plasmodium sp. (P.f. and P.v.) in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
- If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of malaria infection.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) has been tested with microscopy on clinical samples. The results show that the sensitivity of the Malaria P.f/ P.v. Rapid Test Cassette(Whole Blood) is >99.9% when compared to results obtained with microscopy.

Specificity

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) uses antibodies that are highly specific to Malaria P.f.-specific and P. vivax LDH antigens in whole blood. The results show that the specificity of the Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) is >99.9%, when compared to results obtained with microscopy.

Method		Microscopy			Total Results
Malaria P.f./P.v. Rapid Test Cassette	Results	Positive		Negative	
		P. v.	P. f.		
	Positive	54*	85**	0	139
	Negative	1	0	500	501
Total Results		55	85	500	640

Comment : Blood Samples infected by Plasmodium falciparum (n = 85), Plasmodium vivax (n = 54) were included, as well as 500 malaria negative samples to be confirmed with microscopy.

Note: * There was one P. vivax sample to show a P.v. line and a P.f. line.

**there were Two P. falciparum samples that both showed a P.v. line and a P.f. line.

Relative Sensitivity for P.f.-specific antigens: 85/85>99.9 %(95%CI***: 96.5%~100.0%)

Relative Sensitivity for P.v. antigens: 54/55=98.2% (95%CI***: 90.3%~100.0%)

Relative Specificity: 500/500>99.9% (95%CI***: 99.4%-100.0%)

Accuracy: (54+85+500)/ (54+85+1+500) =99.8% (95%CI***: 99.1%-100.0%) *** Confidence Intervals.

Minimum Detection Level

Type	Parasites/µL
P. falciparum	200
P. vivax	1500

Precision Intra-Assay

Within-run precision has been determined by using 15 replicates of four specimens: a negative, a P.f. positive, a P.v. positive and an P.f./P.v. dual positive. The specimens were correctly identified >99% of the time.

Inter-Assay

Between-run precision has been determined by 15 independent assays on the same four specimens: negative, a P.f. positive, a P.v. positive and an P.f./P.v. dual positive. Three different lots of the Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity

The Malaria P.f./P.v. Rapid Test Cassette (Whole Blood) has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, Syphilis, HIV, HCV, H. Pylori, MONO, CMV, Rubella and TOXO positive specimens. The results showed no cross-reactivity.

Interfering Substances

The following potentially interfering substances were added to Malaria negative and positive specimens.

Acetaminophen: 20 mg/dL Caffeine: 20 mg/dL

Acetylsalicylic Acid: 20 mg/dL Gentisic Acid: 20 mg/dL

Ascorbic Acid: 2g/dL Albumin: 2 g/dL

Creatin: 200 mg/dL Bilirubin: 1g/dL

Oxalic Acid: 60mg/dL

None of the substances at the concentrations tested interfered with the assay.

REFERENCES

- Bill MaConell, *Malaria Laboratory Diagnosis*. January 2001.
- Cooke AH, Chiodini PL, Doherty T, et al, Comparison of a parasite lactate dehydrogenase- baseimmunochromatographic antigen detection assay with microscopy for the detection of malaria parasite in human blood samples. *Am J Trop Med Hyp*, 1999, Feb: 60(2):173-2.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry