Malaria Pf/Pan Rapid Test Device
Package Insert

Cat: HIMPN-402 **Specimens:** Whole Blood

Version: 02 **Effective Date:** 2024-06

For professional *in vitro* diagnostic use only.

INTENDED USE

The Malaria Pf/Pan Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of circulating antigens of *Plasmodium falciparum, Plasmodium vivax, Plasmodium ovale, Plasmodium malariae* in whole blood.

SUMMARY

Malaria is caused by a protozoan which invades human red blood cells.[1] World Health Organization estimates that 3.3 billion were at risks of acquiring malaria in 2006, with 247 million of these developing clinical malaria (86% in Africa), and nearly 1 million (mostly African children) dying from the disease. [2] Microscopic analysis of appropriately stained thick and thin blood smears has been the standard diagnostic technique for identifying malaria infections for more than a century.[3] The technique is capable of accurate and reliable diagnosis when performed by skilled microscopists using defined protocols. The skill of the microscopist and use of proven and defined procedures, frequently present the greatest obstacles to fully achieving the potential accuracy of microscopic diagnosis. Although there is a logistical burden associated with performing a time-intensive, labor-intensive, and equipment-intensive procedure such as diagnostic microscopy, it is the training required to establish and sustain competent performance of microscopy that poses the greatest difficulty in employing this diagnostic technology.

The Malaria Pf/Pan Rapid Test Device is a rapid test to qualitatively detect the presence of the *P. falciparum* - specific HRP-II antigens and/or Pan-malarial Lactate Dehydrogenase antigens found in *P. falciparum (P.f), P. vivax (P.v), P. ovale (P.o)* and *P. malariae (P.m)*. The test utilizes colloid gold conjugate to selectively detect *P.f-specific* and *Pan-malarial* antigens *(P.f, P.v, P.o* and *P.m)* in whole blood.

PRINCIPLE

The Malaria Pf/Pan Rapid Test Device (Whole Blood) is a qualitative, membrane based immunoassay for the detection of *P.f, Pan (P.v, P.o and P.m)* antigens in whole blood. The membrane is pre-coated with anti-HRP-II antibodies and anti-Lactate Dehydrogenase antibodies. During testing, the whole blood specimen reacts with the dye conjugate, which has been pre-coated on the test strip. 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-Lactate Dehydrogenase antibodies on the membrane on Pan Line region. If the specimen contains HRP-II or *Plasmodium*-specific Lactate Dehydrogenase or both, a colored line will appear in P.f line region or Pan line region or two colored lines will appear in P.f line region and Pan line region. The absence of the colored lines in P.f line region or Pan line region indicates that the specimen does not contain HRP-II and/or *Plasmodium*-specific Lactate Dehydrogenase. 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.

KIT COMPONENTS

Individually packed test devices Each device contains colored conjugates and reactive reagents pre-spreaded at the corresponding regions

Droppers For adding specimens use

Buffer Phosphate buffered saline and preservative

Package insert For operation instruction

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- For use with whole blood specimen only. Do not use other specimens.
- Do not eat, drink or smoke in the area where the specimens or 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.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

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

SPECIMEN COLLECTION ANDPREPARATION

- The Malaria Pf/ Pan Rapid Test Device (Whole Blood) can be performed using whole blood.
- Both Fingerstick Whole Blood and Venipuncture Whole Blood can be used.
- To collect Fingerstick Whole Blood specimens:
  - Wash the patient's hand with soap and warm water or clean with an alcohol swab. Allow to dry.
  - Massage the hand without touching the puncture site by rubbing down the hand towards the fingertip of the middle or ring finger.
  - Puncture the skin with a sterile lancet. Wipe away the first sign of blood.
  - Gently rub the hand from wrist to palm to finger to form a rounded drop of blood over the puncture site.
- Testing should be performed immediately after specimen collection. Do not leave the specimens at room temperature for prolonged periods. Whole blood collected by venipuncture should be stored at 2-8°C if the test is to be run within 2 days of collection. For long term storage, specimens should be kept below -20°C. Whole blood collected by fingerstick should be tested immediately.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. 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.

MATERIALS

Materials Provided

- Test Devices
- Buffer
- Droppers
- Package insert

Materials Required Not Provided

- Pipette and disposable tips (optional)
- Lancets (for fingerstick whole blood only)
- Specimen collection containers
- Timer

DIRECTIONS FOR USE

Allow the test device, specimen, buffer, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test device from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Transfer the specimen by a pipette or a dropper:
   To use a **Pipette**: Transfer 5 μL of whole blood to specimen well of the test device, and then add 3-4 drops of buffer (approximately 120ul-160ul) to the buffer well, and start the timer.
   To use a **Disposable Specimen Dropper**: Hold the dropper vertically; draw the specimen up to the Fill Line (approximately 5ul). Transfer the specimen to the specimen well, then add 3-4 drops of buffer (approximately 120ul-160ul) to the buffer well and start the timer.
3. Wait for the colored line(s) to appear. The result should **be read at 10 minutes.** Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

Non-*falciparum Plasmodium species* infection: one line appears in the control region and one line appears in Pan line region.

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

***P. falciparum* or mixed malaria infection:** one line appears in the control region, one line appears in Pan line region and one line appears in P.f. line region.

***NOTE:** The intensity of the color in the test line region(s) (Pan or P.f.) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the test line region(s) (Pan and/or P.f.) should be considered positive.

NEGATIVE RESULT:

The colored line in the control line region (C) appears. No line appears in test line regions Pan or P.f..

INVALID RESULT:

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

***NOTE:** The intensity of the color in the test line region(s) (Pan and/or P.f.) will vary depending on the concentration of Dengue antibodies in the specimen. Therefore, any shade of color in the test line region(s) (Pan and/or P.f.) should be considered positive.

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 OF THE TEST

1. The Malaria Pf/ Pan Rapid Test Device (Whole Blood) is for *in vitro* diagnostic use only. This test should be used for the detection of *P.f, Pan (P.v, P.o and P.m)* antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in *P.f, Pan (P.v, P.o and P.m)* concentration can be determined by this qualitative test.
2. The Malaria Pf/ Pan Rapid Test Device (Whole Blood) will only indicate the presence of antigens of *Plasmodium sp.* (*P.f, P.v, P.o, P.m)* in the specimen and should not be used as the sole criterion for the diagnosis of malaria infection.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. 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.

EXPECTED VALUES

The Malaria Pf/ Pan Rapid Test Device (Whole Blood) has been compared with traditional thick or thin microscopic analysis. The correlation between the two systems is 99.4%.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Malaria Pf/ Pan Rapid Test Device (Whole Blood) has been tested with thin or thick microscopy on clinical samples. The results show that the sensitivity of the Malaria P.f/ Pan Rapid Test Device (Whole Blood) is >99.9% relative to microscopy.

Method			Microscopy			Total Results
	Results		Positive		Negative	
			Pan	P. f		
Malaria P.f/ Pan. Rapid Test Device	Positive	Pan	103	0	0	103
		P.f	0	43	2	45
	Negative		0	0	213	213
Total Results			146		215	361

For Pan:

Relative Sensitivity: >99.9% (103/103) (96.5%～100.0%)*

For P.f:

Relative Sensitivity: >99.9% (43/43) (93.3%～100.0%)*

Specificity

The Malaria Pf/ Pan Rapid Test Device (Whole Blood) uses highly specific antibodies for Malaria Pf/ Pan antigens in whole blood. The results show that the specificity of the Malaria Pf/ Pan Rapid Test Device (Whole Blood) is over 99.0% relative to microscopy.

Relative Specificity: 99.1% (213/215)(96.7%～99.9%)*

Accuracy: 99.4% (359/361)(98.0%～99.9%)** 95% Confidence Interval

Note: The comparison for Pan line has been only done with blood specimens positive with *Plasmodium vivax* specimen. The claims for Pan lines are based on scientific findings that Pan-malarial Lactate Dehydrogenase is found in other malarial parasites including *Plasmodium ovale* and *Plasmodium malariae*.

PRECISION

Intra Assay

The run precision has been determined by using 10 replicates of specimens containing negative, low and high positive samples. The negative and positive values were correctly identified >99% of the time.

Inter Assay

Between-run precision has been determined by 3 independent assays on the same five specimens: negative,low positive sample and high positive sample of Malaria *P.f. and P.v* Three different lots of the Malaria Pf/ Pan Rapid Test Device (Whole Blood) have been tested using these specimens. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

1. Bill MaConell, *Malaria Laboratory Diagnosis*. January 2001.
2. Cooke AH, Chiodini PL, Doherty T, et al, *Comparison of a parasite lactate dehydrogenase-base immunochromatographic 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.

Index of Symbols

	Consult instruction for use	Σ	Contains sufficient for <n> tests	EC REP	Authorized Representative
IVD	In vitro diagnostic use		Use-by date	②	Do not re-use
2°C 30°C	Store between 2-30℃	LOT	Batch code	REF	Catalog number
	Do not use if package is damaged	CE	European conformity		

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CE IVD