Malaria Antigen P.f/Pan Rapid Test Cassette (WB)

English

For professional and in vitro diagnostic use only.

[INTENDED USE]

The Malaria Antigen P.f/Pan Rapid Test Cassette is a lateral flow chromatographic immunoassay for the simultaneous detection and differentiation of Plasmodium falciparum (P.f) antigen and P. vivax, P. ovale, or P. malariae (Pan) antigen in human Whole Blood. It provides an aid in the diagnosis of infection with Malaria.

[SUMMARY]

Malaria is caused by a protozoan which invades human red blood cells. 1Malaria is one of the world's most prevalent diseases. According to the WHO, the worldwide prevalence of the disease is estimated to be 300-500 million cases and over 1 million deaths each year. Most of these victims are infants and young children. Over half of the world's population lives in malarious areas. 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. 2The 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 Antigen P.f/Pan Rapid Test Cassette detect antigens to Malaria infection in human Whole Blood. It is a noninvasive method and does not use radioactive isotopes. The test is easy to perform and requires no specialized equipment. Visual interpretation provides an accurate qualitative result. It is a useful on-site aid in the diagnosis of Malaria infection.

[PRINCIPLE]

The Malaria Antigen P.f/Pan Rapid Test Cassette is an immunoassay based on the principle of the double antibody-sandwich technique. In this test procedure, P.f antibody is immobilized in the P.f line, Pan antibody is immobilized in the Pan line. After a Whole Blood specimen is placed in the specimen well, it reacts with Pan antibody and/or P.f antibody coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized antibody. If the specimen contains Pan antigen, a colored line will appear in the Pan line region indicating a Pan positive result. If the specimen contains P.f antigen, a colored line will appear in the P.f line region indicating a P.f positive result. Absence of any T lines (P.f and Pan) suggests a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUSIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test cassette should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

The test contains a membrane strip coated with P.f antibody and Pan antibody on the test line, goat anti mouse antibody on the control line, and a dye pad which contains colloidal gold coupled with P.f antibody and Pan antibody.

The quantity of tests was printed on the labeling.

Materials Provided

•Test cassette •Package insert
•Buffer

Materials Required But Not Provided

•Specimen collection container •Timer

[STORAGE AND STABILITY]

- Store as packaged in the sealed pouch at temperature (4-30℃ or 40-86℉). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

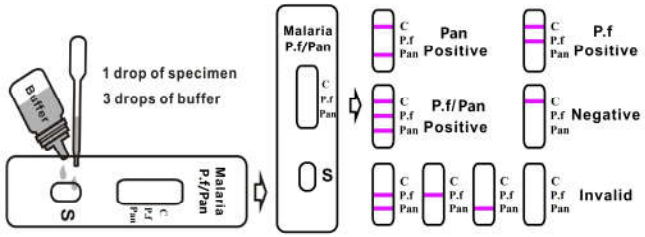
[SPECIMEN]

- The test can be used to test human Whole Blood.
- Collect blood specimen (containing EDTA, citrate or heparin) by vein puncture following standard laboratory procedures.
- Store specimens at 2-8℃ (36-46℉) if not tested immediately. Store specimens at 2-8℃ up to 7 days. The specimens should be frozen at -20℃ (-4℉) for longer storage.
- Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently.

[TEST PROCEDURE]

Allow the test device and specimens to equilibrate to temperature (15-30℃ or 59-86℉) prior to testing.

1. Remove the test cassette from the sealed pouch.
2. Hold the dropper vertically and transfer 1 full drop (approx. 10μl) of specimen to the “S” well of the test cassette, add 3 drops of Sample buffer to the “s” well after the specimen is added, and then begin timing. See the illustration below.
3. Wait for colored lines to appear. Interpret the test results in 15 minutes. Do not read results after 20 minutes.



(The picture is for reference only, please refer to the material object.)

Notes:

Applying sufficient amount of specimen is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop of buffer to the specimen well.

[INTERPRETATION OF RESULTS]

Positive: Control line and at least one test line appear on the membrane. The appearance of Pan test line indicates the Pan positive. The appearance of P.f test line indicates the P.f positive. And if both P.f and Pan line appear, it indicates that the presence of both P.f and Pan positive.

Negative: One colored line appears in the control region (C). No line appears in the test region (T). This negative result indicates the absence of P.f antigen and Pan antigen.

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 cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

[QUALITY CONTROL]

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

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

[LIMITATIONS]

- The Malaria Antigen P.f/Pan Rapid Test Cassette is limited to provide a qualitative detection. The intensity of the test line does not necessarily correlate to the concentration of the antigen in the blood.
- The results obtained from this test are intended to be an aid in diagnosis only. Each physician must interpret the results in conjunction with the patient’s history, physical findings, and other diagnostic procedures.
- A negative test result indicates that antigens to Malaria are either not present or at levels undetectable by the test.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the Malaria Antigen P.f/Pan Rapid Test Cassette and commercially available Malaria P.f/Pan rapid test. 1400 clinical specimens from three Professional Point of Care sites were evaluated with the Malaria Antigen P.f/Pan Rapid Test and the commercial kit. The specimens were checked with a commercially available ELISA to confirm the presence of P.f antigen and Pan antigen in the specimens. The following results are tabulated from these clinical studies:

Agreement with Commercial Malaria P.f/Pan rapid test

P.f test		Commercial Malaria P.f Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	474	1	475
	Negative	2	923	925
Total		476	924	1400

The agreement between these two devices is 99.58% for positive specimens, and 98.89% for negative specimens. This study demonstrated that the Malaria P.f Rapid Test is substantially equivalent to the commercial device.

Pan test		Commercial Malaria Pan Rapid Test		Total
		Positive	Negative	
CLUNGENE®	Positive	471	2	473
	Negative	2	925	927

Total	473	927	1400

The agreement between these two devices is 99.58% for positive specimens, and 98.78% for negative specimens. This study demonstrated that the Malaria Antigen P.f/Pan Rapid Test Cassette is substantially equivalent to the commercial device.

Agreement with ELISA

P.f test		ELISA		Total
		Positive	Negative	
CLUNGENE®	Positive	474	1	475
	Negative	2	923	925
Total		476	924	1400

A statistical comparison was made between the results yielding a clinical sensitivity of 99.58%, a clinical specificity of 99.89% and an accuracy of 99.79%.

Pan test		ELISA		Total
		Positive	Negative	
CLUNGENE®	Positive	474	1	475
	Negative	2	923	925
Total		476	924	1400

A statistical comparison was made between the results yielding a clinical sensitivity of 99.58%, a clinical specificity of 99.78% and an accuracy of 99.71%.

Cross-Reactivity and Interference

1. Potentially cross-reactive endogenous substances including common serum components, such as lipids, hemoglobin, bilirubin, were spiked at high concentrations into the Malaria positive and negative specimens and tested, separately. No cross reactivity or interference was observed to the device.

Analytes	Conc.	Specimens	
		Positive	Negative
Albumin	20mg/ml	+	-
Bilirubin	10μg/ml	+	-
Hemoglobin	15mg/ml	+	-
Glucose	20mg/ml	+	-
Uric Acid	200μg/ml	+	-
Lipids	20mg/ml	+	-

2. Some other common biological analytes were spiked into the Malaria positive and negative specimens and tested separately. No significant interference was observed at the levels listed in the table below.

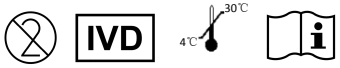
Analytes	Conc. (μg/ml)	Specimens	
		Positive	Negative
Acetaminophen	200	+	-
Acetoacetic Acid	200	+	-
Acetylsalicylic Acid	200	+	-
Benzoylecgonine	100	+	-
Caffeine	200	+	-
EDTA	800	+	-
Ethanol	1.0%	+	-
Gentisic Acid	200	+	-
β - Hydroxybutyrate	20,000	+	-
Methanol	10.0%	+	-
Phenothiazine	200	+	-
Phenylpropanolamine	200	+	-
Salicylic Acid	200	+	-

Reproducibility

Reproducibility studies were performed for the Malaria Antigen P.f/Pan Rapid Test at three physician office laboratories (POL). Sixty (60) clinical specimens, 20 negative, 20 borderline positive and 20 positive, were used in this study. Each specimen was run in triplicate for three days at each POL. The intra-assay agreements were 100% at two sites, and 99.4% at one site. The inter-site agreement was 99.8%.

[Bibliography]

1. Bill McConell, Malaria Laboratory Diagnosis. January 2001
2. Cooke AH, Chiodini PL, Doherty T, et al, Comparison of a parasite lactate dehydrogenase-base immunochro-matographic 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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Index of Symbol

Do not reuse	For in vitro diagnostic use only
Store between 4-30℃	Consult instructions for use
Caution	Lot number
Use by	Contains sufficient for <n> tests
Keep away from sunlight	Keep dry
Manufacturer	Do not use if package is damaged

EC REP Authorized representative in the European Community

Version No.: 3.0
Effective Date: Jul. 30, 2018

Php 92.00 per test