Malaria test

Malaria P.f./P.v./Pan rapid test • cassette • whole blood

ENGLISH

A rapid test for the qualitative detection of circulating antigens of P. falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.) in whole blood.
For professional in vitro diagnostic use only.

[INTENDED USE]
The Malaria P.f./P.v./Pan rapid test is a rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating Plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.) in whole blood.

[SUMMARY]
Malaria is caused by a protozoan which invades human red blood cells.[1] Malaria 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, 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.[2] 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, labour-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 P.f./P.v./Pan rapid test is a rapid test to qualitatively detect the presence of P. falciparum - specific HRP-II, P. vivax (P.v.) and four kinds of circulating plasmodium falciparum (P.f.), P. vivax (P.v.), P. ovale (P.o.), and P. malariae (P.m.). The test utilises colloid gold conjugate to selectively detect P.f-specific, P. vivax (P.v.) and Pan-malarial antigens (P.f., P.v., P.o. and P.m.) in whole blood.

[PRINCIPLE]
The Malaria P.f./P.v./Pan rapid test is a qualitative, membrane based immunoassay for the detection of P.f., P.v., P.o. and P.m. antigens in whole blood. The membrane is pre-coated with anti-HRP-II antibodies, anti-p.v. LDH and anti-pan LDH 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, with anti-p.v. LDH antibodies on the membrane on P.v. line region and with anti-pan LDH antibodies on the membrane on Pan line region. If the specimen contains HRP-II, p.v. LDH and/or pan LDH, coloured line (s) will appear in P.f. line region, P.v. and/or Pan line region. The absence of the coloured lines in P.f. line region, P.v. line region and/or Pan line region indicates that the specimen does not contain HRP-II, P.v. LDH and/or Plasmodium-specific LDH. To serve as a procedure control, a coloured line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

[REAGENTS]
The test cassette contains anti-HRP-II of plasmodium falciparum antibodies conjugated gold, anti-LDH of P. vivax antibodies and anti-Plasmodium falciparum LDH antibodies conjugated gold and anti-HRP-II antibodies, anti-P.v. LDH and anti-Plasmodium-specific LDH antibodies coated on the membrane

[PRECAUTIONS]
- 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 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 labouratory 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.
- Do not exchange or mix buffer and test cassettes from kits of different lots.
- Caution must be taken at the time of specimen collection. Inadequate volume of specimen may lead to lower sensitivity.
- Be sure to add sufficient buffer to the cassette's sample well. Invalid result may occur if inadequate buffer is added.

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

[SPECIMEN COLLECTION AND PREPARATION]
- The Malaria P.f./P.v./Pan rapid test 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

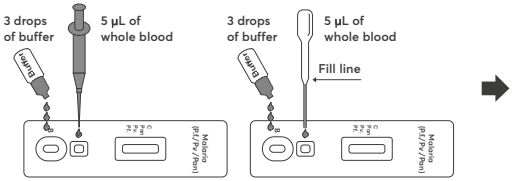
• Test cassettes
• Buffer
• Disposable transfer dropper
• Package insert

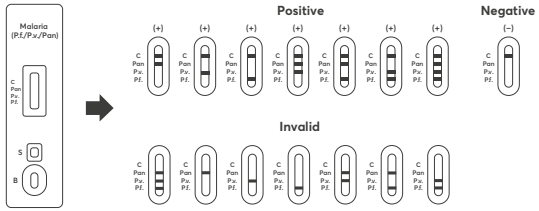
Materials required but not provided

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

[DIRECTIONS FOR USE]
Allow the test, specimen, buffer and/or controls to reach room temperature (15-30°C) 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.
   • Use a pipette: To transfer **5μL of whole blood** to the specimen well (S), then add **3 drops of buffer** (approximately 180μL) to the buffer well (B) and start the time.
   • Use a disposal transfer tube: Hold the tube vertically; draw the specimen up to the upper end of the nozzle as shown in illustration below (approximately 5uL). Transfer the specimen to the specimen well (S), then add **3 drops of buffer (approximately 180μL)** to the buffer well (B) and start the timer.
3. Wait for the coloured 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 above)

POSITIVE:* Two or Three or Four distinct coloured lines appear.
P. falciparum Infection (Either of the results):
• One line appears in the control region, one line appears in P.f. line region.
• One line appears in the control region, one line appears in P.f. line region and one line appears in Pan line region.
P. vivax Infection (Either of the results):
• One line appears in the control region, one line appears in P.v. line region.
• One line appears in the control region, one line appears in P.v. line region and one line appears in Pan line region.
Non-P. falciparum/ Non-P. vivax Infection:
• One line appears in the control region, one line appears in Pan line region.
Mixed malaria infection:
• One line appears in the control region, one line appears in P.f. line region, and one line appears in P.v. line region.
• One line appears in the control region, one line appears in P.f. line region, one line appears in P.v. line region and one line appears in Pan line region.
***NOTE:** The colour intensity of P.f., P.v. or Pan Test lines may vary depending on the concentration of antigens, viz., HRP-II, P.v. LDH or Plasmodium-specific LDH present in the specimen.
NEGATIVE: Only one coloured 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.

[QUALITY CONTROL]
Internal procedural controls are included in the test. A coloured 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 labouratory practice to confirm the test procedure and to verify proper test performance.

[LIMITATIONS]
1. The Malaria Test P.f./P.v./Pan rapid test is for *in vitro* diagnostic use only. This test should be used for the detection of P.f., P.v., P.o., P.m. antigens in whole blood specimens only. Neither the quantitative value nor the rate of increase in P.f., P.v., P.o., and P.m. concentration can be determined by this qualitative test.
2. The Malaria Test P.f./P.v./Pan rapid test 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.pathogen, therefore the possibility of an underlying bacterial infection should be considered.

[EXPECTED VALUES]
The Malaria Test P.f./P.v./Pan rapid test has been compared with traditional thick and thin blood films microscopic analysis. The correlation between the two systems is over 99.0%.

[PERFORMANCE CHARACTERISTICS]

Sensitivity
The Malaria Test P.f./P.v./Pan rapid test has been tested with microscopy on clinical samples. The results show that the sensitivity of the the Malaria Test P.f./P.v./Pan rapid test is >98.7% when compared to results obtained with microscopy.

Specificity and Accuracy
The Malaria Test P.f./P.v./Pan rapid test uses antibodies that are highly specific to Malaria P.f.-specific, Malaria P.v.-specific and Pan-malarial antigens in whole blood. The results show that the specificity of the Malaria Test P.f./P.v./Pan rapid test is >99.0%, when compared to results obtained with microscopy.

Method		Microscopy		Total Results
	Results	Positive	Negative	
Malaria P.f./P.v./Pan Rapid Test Cassette	Positive	77	1	78
	Negative	1	148	149
Total Results		78	149	227

Relative sensitivity: 98.7% (95%CI*: 93.1%~100%)
Relative specificity: 99.3% (95%CI*: 96.3%~100%)
Accuracy: 99.1% (95%CI*: 96.8%~99.9%) *Confidence intervals

Precision
Intra-Assay
Within-run precision has been determined by using 3 replicates of ten specimens: negative, P.f. low positive, P.f. middle positive, P.f. high positive, P.v. low positive, P.v. middle positive, P.v. high positive, Pan low positive, Pan middle positive, Pan high positive. The specimens were correctly identified >99% of the time.

Inter-Assay
Between-run precision has been determined by 3 independent assays on the same ten specimens: negative, P.f. low positive, P.f. middle positive, P.f. high positive, P.v. low positive, P.v. middle positive, P.v. high positive, Pan low positive, Pan middle positive, Pan high positive. Three different lots of the Malaria Test P.f./P.v./Pan rapid test have been tested using these specimens. The specimens were correctly identified >99% of the time.

Cross-reactivity
Malaria Test P.f./P.v./Pan rapid test has been tested by HAMA, RF, HBsAg, HBsAb, HBeAg, HBeAb, HBcAb, anti-syphilis, anti-HIV, anti-HCV, anti-H. Pylori, anti-MONO, anti-CMV IgM, anti-rubella IgM and anti-TOXO IgM positive specimens. The results showed no cross-reactivity.

Interfering substances
The following potentially interfering substances were added to malaria negative and positive specimens.
acetaminophen: 20mg/dL
acetylsalicylic Acid: 20mg/dL
ascorbic Acid: 2g/dL
creatin: 200mg/dL
caffeine: 20mg/dL
gentisic acid: 20mg/dL
albumin: 2g/dL
bilirubin: 1g/dL
oxalic acid: 60mg/dL

None of the substances at the concentration tested interfered in the assay.

[BIBLIOGRAPHY]

1. 1. Bill MaConell, Malaria Labouratory 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

	Caution	Σ	Tests per kit	EC REP	Authorised Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalogue #
	Do not use if package is damaged		Consult Instructions for Use		Manufacturer

CE

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