Accu-Screen Malaria P.f./Pan Antigen Test Device Package Insert

A rapid test for qualitative detection of circulating antigens of P.falciparum(P.f.) and Pan-LDH(Pan) in Whole Blood.
For professional in vitro diagnostic use only

INTENDED USE

The Malaria P.f./Pan Antigen Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of two kinds of circulating plasmodium falciparum(P.falciparum(P.f.)and Malaria pan lactate dehydrogenase (PAN-LDH) in whole blood.

SUMMARY

Malaria is caused by a protozoan which invades human red blood cells 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.The technique is capable of accurate and reliable diagnosis when performed by skilled microscopists using defined protocols. The skill of the microscopists and use of proven and defined procedures,frequently present the greatest obstades 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 P.f./Pan Antigen Rapid Test Device is a rapid test to qualitatively detect the presence of P falciparum-specific-HRP and Pan-LDH(Pan).The test utilizes colloid gold conjugate to selectively detect P.f-specific and Pan-LDH(Pan)-specific antigens in whole blood.

PRINCIPLE

The Malaria P.f/Pan Antigen Rapid Test Device is a qualitative,membrane based immunoassay for the detection of P.f. and Pan antigens in whole blood.The membrane is pre-coated with anti-HRP-II antibodies and monoclonal antibody is pan to the lactate dehydrogenase of Plasmodium species.During testing the whole blood specimen reacts with the dye conjugate,which has been pre-coated on the test device.The mixture then migrates upward on the membrane by capillary action,reacts with anti-histidine-rich Protein I(HRP-II)antibodies on the membrane on P f Test Line region and with anti-pan-LDH antibodies on the membrane on Pan Line region.If the specimen contains HRP-II or plasmodium-specific Pan LDH 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 Pan-LDH.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.

REAGENTS

The test device contains anti-HRP-II of Plasmodium falciparum antibodies conjugated gold and anti-Pan-LDH antibodies conjugated gold and anti-HRP-II antibodies and anti-PAN-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 laboratory coats,disposable gloves and eye protection when specimens are assayed.
- The used tests,specimens and potentially contaminated materials should be discarded according to the local regulations.
- Humidity and temperature can adversely affect results.
- Do not exchange or mix buffer and test devices 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.
- Be sure to add sufficient buffer to the Device's sample well.Invalid result may occur if inadequate buffer is added For best results,adhere to instructions provided.

STORAGE AND STABILITY

The kit can be stored at room temperature or refrigerated(2-30℃).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 AND PREPARATION

- The Malaria P.f./Pan Antigen Rapid Test Device can be performed using whole blood(from venipuncture or fingerstick).
- 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.
  - Add the Fingerstick Whole Blood specimen to the test by using a **capillary tube:**
    - Touch the end of the capillary tube to the blood until filled to approximately 5μL.Avoid air bubbles.
    - Place the bulb onto the top end of the capillary tube,then squeeze the bulb to dispense the whole blood to the specimen area of the test Device.
- Testing should be performed immediately after the specimens have been collected.Do not leave the specimens at room temperature for prolonged periods.Whole blood collected by venipuncture should be stored at 2-8℃ if the test is to be run within 1 day of collection.Do not freeze whole blood specimens.Fingerstick Whole blood collected by capillary tube 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.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.

MATERIALS

Materials provided

- Test device
- Buffer
- Dropper
- Package insert

Materials required but not provided

- Specimen collection containers
- Timer
- Heparinized capillary tubes and dispensing bulb
- Centrifuge (for plasma only)
- Lancets (for finger stick whole blood only)

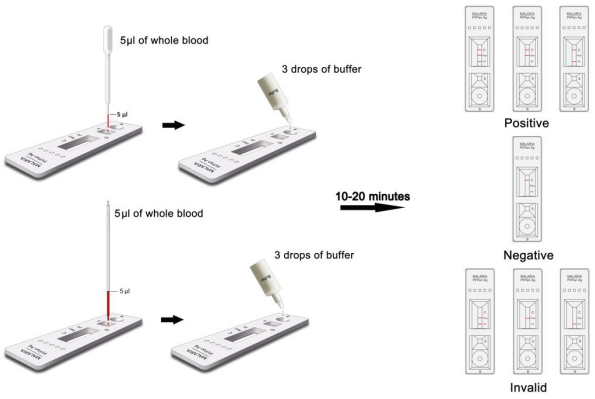
DIRECTIONS FOR USE

Allow the test, specimen,buffer and/or controls to reach room temperature (15-30℃) prior to testing.

1. Bring the pouch to room temperature before opening it.Remove the test Device from the sealed pouch and use it as soon as possible.
2. Place the Device on a clean and level surface.

- For **Venipuncture Whole Blood specimen:**Hold the dropper vertically and **transfer 5μL whole blood** to the specimen area,then **add 3 drops of buffer (approximately 120μL)**, and start the timer.See illustration below.
- For **Fingerstick Whole Blood specimen:**To use a capillary tube:Fill the capillary tube and **transfer approximately 5μL of fingerstick whole blood specimen** to the specimen area of test device,then **add 3 drops of buffer (approximately 120μL)** and start the timer.See illustration below.

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 above)

POSITIVE:P. f. Positive:A red line appears in the control line region (C)and another red line appears in the P.f. line region.
Pan Positive:A red line appears in the control line region (C)and another red line appears in the Pan line region.
P.f. and Pan Positive:A red line appears in the control line region (C)and two other red lines appears in P.f. line region and Pan line region respectively.
NOTE: The intensity of the color in the test line region will vary depending on the concentration of P.f. or Pan antigens present in the specimen.Therefore,any shade of color in the test line region should be considered positive.
NEGATIVE: No red line appears in the test line region.A distinct pink line shows on the control line region (C).
INVALID:No line appears in the control line region (C). If this occurs,read the directions again and repeat the test with a new test.If the result is still invalid,stop 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 line region (C) is considered an internal procedural control. 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

1. The Malaria P.f./Pan Antigen Rapid Test Device is for in vitro diagnostic use only.This test should be used for the detection of P.f. and Pan antigens in whole blood specimens only.Neither the quantitative value nor the rate of increase in P.f. and Pan concentration can be determined by this qualitative test.
2. The Malaria P.f./Pan Antigen Rapid Test will only indicate the presence of antigens of Plasmodium sp. (P.f. and pan) 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 P.f./Pan Antigen Rapid Test Device 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 P.f./Pan Antigen Rapid Test Device has been tested with microscopy on clinical samples.The results show that the overall sensitivity of P.falciparum and Pan were >99.9% and 98.0% when compared to results obtained with microscopy.

Specificity

The Malaria P.f./Pan Antigen Rapid Test Device uses antibodies that are highly specific to Malaria P.f.-specific and Pan LDH antigens in whole blood.The results show that the specificity of the Malaria P.f./Pan Antigen Rapid Test Device is>99.9%,when compared to results obtained with microscopy.

Method		Microscopy			
		Positive		Negative	Total Results
	Results	Pan	P.f.		
Malaria P.f./Pan Rapid Test	Positive	50*	82**	0	132
	Negative	1	0	432	433
Total Results		51	82	432	565

Comment: Blood Samples infected by Plasmodium falciparum(n=82),Plasmodium an-LDH(n=51)were included,as well as 432 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 they both showed a pan line and a P.f. line.
Relative Sensitivity for Pf. specific antigens:82/82>99.9%(95%CI***: 96.4%-100.0%)
Relative Sensitivity for pan antigens: 50/51=98.0%(95%CI ***: 89.6%-100.0%)
Relative Specificity: 432/432>99.9%(95%CI***: 99. 3%-100.0%)
Accuracy:(50+82+432)(82+51+432)=564/565=998%(95%CI"*:99.0%-100.0%)
***Confidence Intervals

Minimum Detection Level

Type	Parasites/ul
P.falciparum	200
Pan-LDH	1500

Precision

intra-assay

Within-run precision has been determined by using 15 replicates of four specimens.a negative, p.f. positive,a Pan positive and a p.f./pan 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 pan positive and a p.f./pan dual positive.Three different lots of Malaria P.f./Pan Antigen Rapid Test Device have been tested using these specimens.The specimens were correctly identified >99% of the time.

Cross-reactivity

The Malaria P.f./Pan Antigen Rapid Test device have been by HAMA,RF,HBsAg,HBsAb,HBeAg,HBeAb,HBcAb,HCV,HIV,Syphilis,H.Pylori,CMV and Rubella positive specimens.The results showed no cross-reactivity.

Interfering Substance

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

Acetaminophen: 20 mg/dl	Acetylsalicylic Acid: 20 mg/dl	Ascorbic Acid: 2g/dl
Creatin: 200 mg/dl	Oxalic Acid: 60mg/dl	Caffeine: 20 mg/dl
Gentisic Acid: 20 mg/dl	Albumin: 2 g/dl	Bilirubin: 1g/dl

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

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SYMBOLS

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number		Contains sufficient for <n> tests

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