CLEARTEST® DIAGNOSTIK

CLEARTEST® Malaria P.f./Pan

A rapid test for the qualitative detection of circulating antigens of P. falciparum (P.f.) and for differentiation from other less virulent malaria pathogens Pani (P.v.), (P.o.), (P.m.) in whole blood.

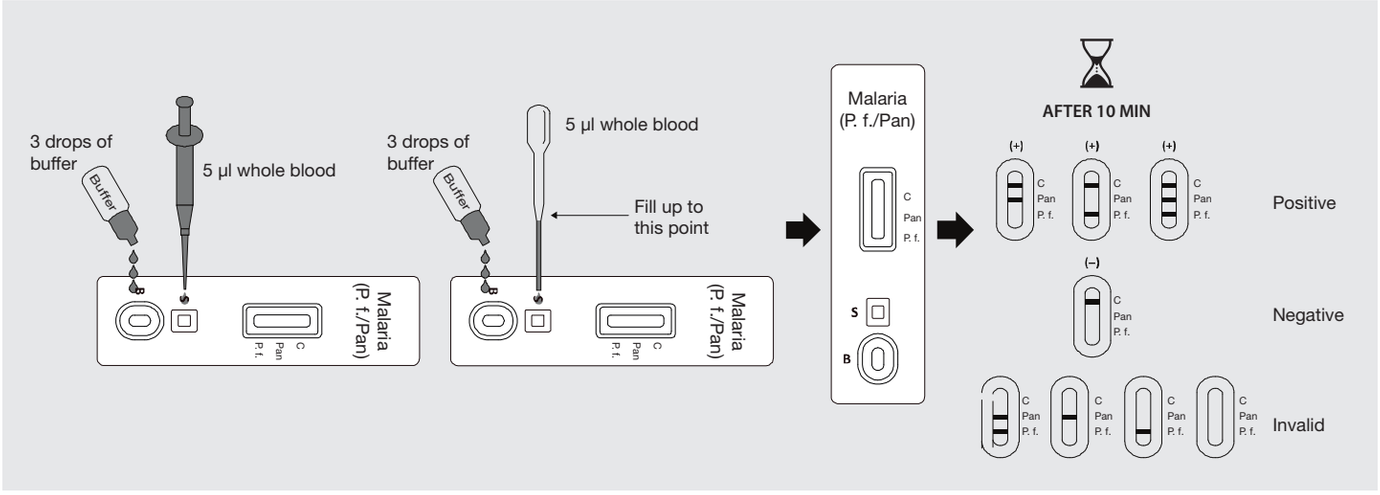
For professional in vitro diagnostic use only

INSTRUCTIONS FOR USE

CE IVD

INTENDED USE

The CLEARTEST® Malaria P.f./Pan (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of four kinds of circulating plasmodium falciparum (P. 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, 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 CLEARTEST® Malaria P.f./Pan (Whole Blood) is a rapid test to qualitatively detect the presence of P. falciparum - specific HRP-II and four kinds of circulating plasmodium falciparum(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 CLEARTEST® Malaria P.f./Pan (Whole Blood) 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 and anti-Aldolase 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-Aldolase antibodies on the membrane on Pan Line region. If the specimen contains HRP-II or Plasmodium-specific Aldolase 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 Aldolase. 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 cassette contains anti-HRP-II of Plasmodium falciparum antibodies conjugated gold and anti-Plasmodium falciparum Aldolase antibodies conjugated gold and anti-HRP-II antibodies and anti-Aldolase 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 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 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 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 CLEARTEST® Malaria P.f./Pan (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 cassettes
- Disposable specimen droppers
- Buffer
- Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

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

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.

For Whole Blood specimen:

- Use a pipette: To transfer 5 µL of whole blood to the specimen well, then add 3 drops of buffer (approximately 180 µL).
- Use a disposal specimen dropper: Hold the dropper vertically, draw the specimen up to the Fill Line as shown in illustration on the first page (approximately 5 µL). Transfer the specimen 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 on front page)

POSITIVE:* Two or Three distinct colored lines appear.

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.

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 Pan line region.

***NOTE:** The color intensity of P.f. or Pan test lines may vary depending on the concentration of antigens, viz., HRP-II or Aldolase 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.

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

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

Specificity

The CLEARTEST® Malaria P.f./Pan (Whole Blood) uses antibodies that are highly specific to Malaria P.f.-specific and Pan-malarial antigens in whole blood. The results show that the specificity of the CLEARTEST® Malaria P.f./Pan (Whole Blood) is >99.9%, when compared to results obtained with microscopy.

Method		Mikroscopy			Total Results
CLEARTEST® Malaria P.f./Pan	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 they 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
Plasmodium non-falciparum-Art (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 Pan positive and an 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 an P.f./Pan dual positive. Three different lots of the CLEARTEST® Malaria P.f./Pan (Whole Blood) have been tested using these specimens. The specimens were correctly identified >99% of the time.

CROSS-REACTIVITY

The CLEARTEST® Malaria P.f./Pan (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
Ascorbic Acid: 2 g/dL
Caffeine: 20 mg/dL
Albumin: 2 g/dL
Oxalic Acid: 60 mg/dL
Acetylsalicylic Acid: 20 mg/dL
Creatin: 200 mg/dL
Gentisic Acid: 20 mg/dL
Bilirubin: 1g/dL

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

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			
REF	Article number		Temperature limitation
	Observe operating instructions	LOT	Batch number
IVD	In-vitro-diagnostic		Expiry date
	Manufacturer		Content sufficient for <n> tests
	Dangerous substances		Single use
	Protect from heat and sunlight		Attention
	Protect from moisture		
	Do not use, if package is damaged		
CE	CE marked according to IVD directive 98/79/EG		

ORDERING INFORMATION

CLEARTEST® Malaria P.f./Pan

REF C3 4600, 5 Test cassettes, PZN 16486223

IVD CE

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1-C3 4600-222-2-0001.1-2105

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