One Step Rapid Test for Malaria Antigen Pf/Pan

MaxLINE Malaria Antigen Pf/Pan Rapid Test

Whole Blood Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVMALWB1-10	10 Tests
AVMALWB1-20	20 Tests
AVMALWB1-25	25 Tests
AVMALWB1-30	30 Tests
AVMALWB1-50	50 Tests

NOTE : 10T, 20T, 25T, 30T Pack Sizes are not available for domestic trade.

INTENDED USE

MaxLINE Malaria Antigen Pf/Pan Rapid Test is Immunochromatographic test for the detection of Malaria Antigen Pf/Pan in human Whole Blood sample.

PRODUCT FEATURES

1. MaxLINE Malaria Antigen Pf/Pan whole blood test is a rapid and self performing test.
2. MaxLINE Malaria Antigen detection is based on immuno chromatographic assay.
3. Qualitative, two side sandwich immunoassay, utilizing whole blood for the detection of P.falciparum specific histidine rich protein-2 (HRP-II) and Pan specific pLDH.
4. Facilitates differential diagnosis of mixed infection and confirm for differential diagnosis between Plasmodium falciparum and other Plasmodium species (P. vivax, P. ovale, P. Malariae) and monitoring of treatment all in one step.
5. Specificity 99.7% and no cross reactivity.
6. Sensitivity 100%.
7. High-tech membrane strip locks in visible test results at ambient conditions even months later.
8. Longer shelf life up to 24 months.
9. Result within 15-25 minutes.

INTRODUCTION

MaxLINE Malaria Antigen Pf/Pan device is a self performing and rapid Chromatographic Immunoassay test device, using whole blood for the detection of *P. falciparum* specific histidine rich protein-2 (Pf HRP-2) and Plasmodium lactate dehydrogenase (Pan specific pLDH). It may also be used for differentiation of Pf and other malarial species. Malaria is one of the leading public health problems in world wide. It is a serious, sometimes fatal, parasitic disease characterized by fever, chills, and anaemia and is caused by a parasite that is transmitted from one human to another by the bite of infected Anopheles mosquitoes. The disease now occurs in more than 90 countries worldwide, and it is estimated that there are over 500 million clinical cases and 2.7 million malaria-caused deaths per year. MaxLINE Malaria Antigen is a visual, rapid and sensitive immunoassay for the qualitative differential detection of P. *falciparum* and other malarial species in Human Blood only.

PRINCIPLE

MaxLINE Malaria Ag is a rapid test device assay, as the whole blood flows through the Nitrocellulose membrane assembly after addition of assay buffer, the anti Pf HRP-2 specific, Anti Pan Specific and Rabbit IgG colloidal gold conjugate antibodies complexes the proteins in the lysed sample. Colloidal gold conjugate moves further on the Nitrocellulose membrane to the test region where it immobilized by the Anti Pf. HRP-2 and anti Pan specific antibodies coated on the nitrocellulose membrane leading to the formation of Coloured bands which confirms a positive.
If both the bands Pf & Pan appear together, the blood sample is infected with falciparum. If only one Pan Band is appear in non falciparum malaria positive samples. Absence of both coloured lines indicates a negative test. Appearance of Coloured band at the control line C serves to validate the test performance.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (4-30°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.

KIT CONTAINS

Ref. No.	Pack Size	Test Device	Buffer Vial	Product Insert
AVMALWB1-10	10 Tests	10 Nos.	1 No.	1 No.
AVMALWB1-20	20 Tests	20 Nos.	1 No.	1 No.
AVMALWB1-25	25 Tests	25 Nos.	1 No.	1 No.
AVMALWB1-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVMALWB1-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

a) Individually packed Test Devices
b) Buffer Vial
c) Sample Droppers
d) Product insert

2. Materials Required But Not Provided

- Calibrated micropipette capable of delivering 5 µl samples
- Stop Watch
- Sample Collection Container
- Lancet
- Swab

PRECAUTIONS

1. The device is sensitive to humidity as well as to heat. So it's very important to take off the device from the sealed pouch when it use.
2. Do not use the kit after the expiration date.
3. For in vitro diagnostics use only.
4. Wear protective gloves while handling samples and wash hands thoroughly after the test.
5. Dispose all the samples and kits properly after test, in accordance with GLP.
6. Do not pipette reagent or blood by mouth.

SPECIMEN COLLECTION AND STORAGE

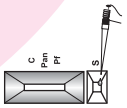
1. The test should be performed with freshly collected human blood collected from the fingertip or by venipuncture using sample tube containing anticoagulant.
2. For the short term storage, please keep the specimen at 2-8° C, for the long term storage; please keep the sample below - 20° C.

TEST PROCEDURE

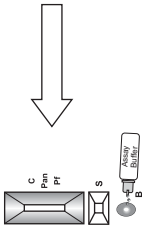
1. Clean the fingertip with the alcohol swab, and let dry completely. Prick the fingertip with a single use lancet.
2. Collect 5 µl of blood using the sample dropper up to the mark or pipette.
3. Load the 5 µl of blood into the sample well"S" of the test device.
4. Add 3 drops (100 ul) of assay buffer into the assay buffer well, "B" of the test device.
5. Interpret test results at 15-25 minutes. The results should not be interpreted after 25 minutes.
6. Refer to the following pictures for analysis of the test result.

INTERPRETATION OF RESULTS

USE ONLY WHOLE BLOOD SAMPLE



5µl Whole Blood



Add 3 Drop of Assay Buffer

* Special Instruction *
Add 5µl Whole Blood and 3 drop Assay Buffer

15 - 25 Minutes

Negative: One bands appears in Window "C" Region

Pf Positive: Two bands appears in Window "C" and "Pf" Region

Pan POSITIVE: Two bands appears in Window "C" and "Pan" Region

Pf/Pan POSITIVE: Three bands appears in Window "C", "Pan" and "Pf" Region

INVALID: No bands appears in Window Region. The Result is considered invalid

INVALID: The result should also be considered invalid if only test band (Pan & Pf) appears and no control band appears in window region.

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. 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 a good laboratory practice to confirm the test procedure and to verify proper test performance.

EXPECTED VALUES
The Malaria Antigen Pf/Pan Rapid Test has been compared with a leading commercial Malaria Antigen Pf/Pan test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS
500 Samples whose Result were earlier confirmed by microscopy were tested with MaxLINE Malaria Antigen Pf/Pan. The Result are given below :-

Specimen	Number of Sample	Positive	Negative
P.falciparum	60	60	0
P. vivax	55	55	0
Negative	385	1	384

Sensitivity:100% Specificity - 99.70%

PRECISION
Intra-Assay
Within-run precision has been determined by testing 15 replicates of three specimens : a negative, a low positive and a high positive. The negative, low positive and high positive values were correctly identified 99% of the time.

Inter-Assay
Between-run precision has been determined by testing 15 replicates on the same three specimens : a negative, a low positive and a high positive. Three different lots of the Malaria Rapid Test Device (Whole Blood) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

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

Acetaminophen:	20 mg/dL	Caffeine:	20 mg/dL
Acetylsalicylic Acid:	20 mg/dL	Gentisic Acid:	20 mg/dL
Ascorbic Acid:	2g/dL	Albumin:	2 g/dL
Creatin:	200 mg/dL	Hemoglobin	1.1 mg/dL
Bilirubin:	1g/dL	Oxalic Acid:	600mg/dL

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

LIMITATIONS OF THE TEST
Detection limit of this kit is 100 parasites/µl of blood for Pf and 200 parasites/µl of the blood for Pan. Malaria Pf/Pan test is designed for primary screening test of malaria infection. This kit can provide fast and easy way to get a result, but do not completely exclude the possibility of false positive or false negative result caused by various factors. So, refer to the result of this kit, please make a final decision with clinical manifestation, other test results, and doctor's view, collectively.

DISCLAIMER:
The manufacturer has take every precaution to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the Manufacturer and Distributor and the result may accordingly be affected by user error and/or environmental factors. A person who is the subject of the diagnosis should consult a clinician for further confirmation of the result.

WARNING:
The Manufacturer and Distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect or consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.

REFERENCES

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Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test

Manufactured in India by :
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