

One Step Rapid Test for Malaria Antigen Pf/Pv MaxLINE Malaria Antigen Pf/Pv Rapid Test Whole Blood Test Protocol

ORDERING INFORMATION

Ref. No.	Pack Size
AVMALWB2-10	10 Tests
AVMALWB2-20	20 Tests
AVMALWB2-25	25 Tests
AVMALWB2-30	30 Tests
AVMALWB2-50	50 Tests

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

INTENDED USE

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

PRODUCT FEATURES :

1. MaxLINE Malaria Antigen is rapid one step malaria Pf/Pv whole blood 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 Pv specific pLDH.
4. Specificity 99.75% and no cross reactivity.
5. Sensitivity 100% .
6. High-tech membrane strip locks in visible test results at ambient conditions even months later.
7. Longer shelf life up to 24 months.
8. Result within 15-25 minutes.

INTRODUCTION

Malaria Antigen Pf/Pv 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 (Pv specific pLDH). It may also be used for differentiation of Pf and Pv 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. Malaria Antigen Pf/Pv is a visual, rapid and sensitive immunoassay for the qualitative differential detection of *P. falciparum* and *P. vivax* malaria antigen in Human Blood only.

PRINCIPLE

Malaria Ag Pf/Pv 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 Pv 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 Pv specific antibodies coated on the nitrocellulose membrane leading to the formation of Coloured bands which confirms a positive.

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
AVMALWB2-10	10 Tests	10 Nos.	1 No.	1 No.
AVMALWB2-20	20 Tests	20 Nos.	1 No.	1 No.
AVMALWB2-25	25 Tests	25 Nos.	1 No.	1 No.
AVMALWB2-30	30 Tests	30 Nos.	2 Nos.	1 No.
AVMALWB2-50	50 Tests	50 Nos.	3 Nos.	1 No.

MATERIALS

1. Materials Provided

Each kit contains :

- a) Individually packed test device
- b) Buffer
- c) Sample Dropper
- d) Product insert

2. Materials Required But Not Provided

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

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:

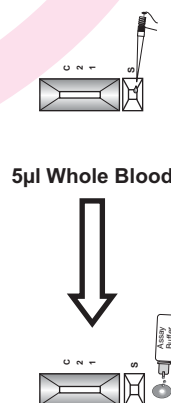
1. The test should be performed with freshly collected human blood, collected from the fingertip or by venipuncture using sample tube containing anticoagulant.
2. For the short term storage, please keep the specimen at 2-8° C, for the long term storage; please keep the sample below - 20° C.

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 upto the mark.
3. Load the 5 µl of blood into the sample well "S" of the test device.
4. Add 3 drops (75 µl) of assay buffer (Diluent) 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.

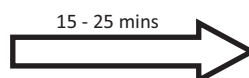
INTERPRETATION OF RESULTS

Use Only Whole Blood Sample



Add 3 Drops of Assay Buffer

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



Negative: One bands appears in Window "C" Region



Pf Positive: Two bands appears in Window "C" and "1" Region



Pv POSITIVE: Two bands appears in Window "C" and "2" Region



Pf/Pv POSITIVE: Three bands appears in Window "C", "2" and "1" 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 (2 & 1) 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/Pv Rapid Test has been compared with a leading commercial Malaria Antigen Pf/Pv test, demonstrating an overall accuracy greater than or equal to 99.7%.

PERFORMANCE CHARACTERISTICS

540 Samples whose Result were earlier confirmed by microscopy were tested with MaxLINE Anitgen. The Result are given below :-

Specimen	Number of Sample	Positive	Negative
P. falciparum	60	60	0
P. vivax	80	80	0
Negative	400	1	399

Sensitivity : 100%

Specificity - 99.75%

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

Detection limit of this kit is 100 parasites/μl of blood for Pf and 200 parasites/μl of blood for Pv Malaria Pf/Pv 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

1. Baker J., etal, Olos one, 6(7), 2011, 1-10.
2. Clinton, K. etal, Interscriplinary Prespective on Infections Diseases, 1155, 2009, 1-7.
3. Howard R. J. etal, J.Cell Biol, 103, 1986, 1269-1277.
4. Moody, A., Clinical Microbiological Review, 15(1), 2002, 66-78.
5. Malcolm, J.G. etal, 2002, Nture 419, 2002, 498-511
6. Perlmann, P. and Troye-Blomberg, M. 2002.. Malaria parasites and disease. Malaria Immunology.
7. Pipe, R. G., etal, Malaria Journal, 10/(213) 2011, 2-14.
8. Warhurst, D.C., and J.E. Williams, J Clin. Patol 49, 1996, 533-538.
9. World Health Orngaization-Geneva, New Perspective malaria diagnosis 2000.

Symbols Used on Pack

 REF	Catalogue Number		Warning/Caution
 LOT	Batch No.		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



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