

TMDA/DMD/MDA/F/014
Rev #:00



THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH



TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

**PUBLIC ASSESSMENT REPORT FOR MAXLINE MALARIA ANTIGEN PF/PAN RAPID
TEST**

Version number 2.0, 18.05.2026

**TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box
1253, Dodoma – Tanzania, Telephone: +255 (26) 2961989/2061990/+255 (22)
2450512/2450751/2452108, Email: info@tmda.og.tz, Website: www.tmda.go.tz**

Toll free: 0800110084

1. Introduction

Maxline is a class C in-vitro diagnostic device belonging to the parasitology specialty category. It is approved in Tanzania as a kit for use in adults, children, elderly etc. by healthcare professionals.

1.1. Administrative Information

Registration number	TAN 25 MDR 0274
Brand Name (if relevant)	MAXLINE
Common name	Malaria Antigen P.f/Pan Rapid Test
Class of the device and rule applied	Class D as per Rule 1 for classification of In Vitro Diagnostic Devices.
GMDN code and term	52311, Multiple Plasmodium species antigen IVD, kit, rapid ICT, clinical
Name and complete address of the Market Authorization Holder	Malulu Company Limited, Address: P.O. Box 850, NSSF Uchumi Complex, Agakhan Road Kilimanjaro.
Name and address(es) of local responsible person (LRP).	Name: Malulu Company Limited Address: P.O. Box 850, NSSF Uchumi Complex, Agakhan Road, Kilimanjaro.

1.2. Assessment Procedure

The application for registration of Maxline was submitted on 01.07.2024. The product underwent full assessment. Assessment was completed in six (6) rounds of evaluation. Maxline was registered on 28.11.2025

2. Technical information

2.1. Intended use

The intended use of Maxline as declared by the manufacturer and approved by TMDA is a single test device used for is Immunochromatographic test for the detection of Malaria Antigen P.f/Pan in human whole blood sample. Maxline is approved for use in healthcare settings, point of care by both trained personnel or laypersons.

2.2. Device details and features

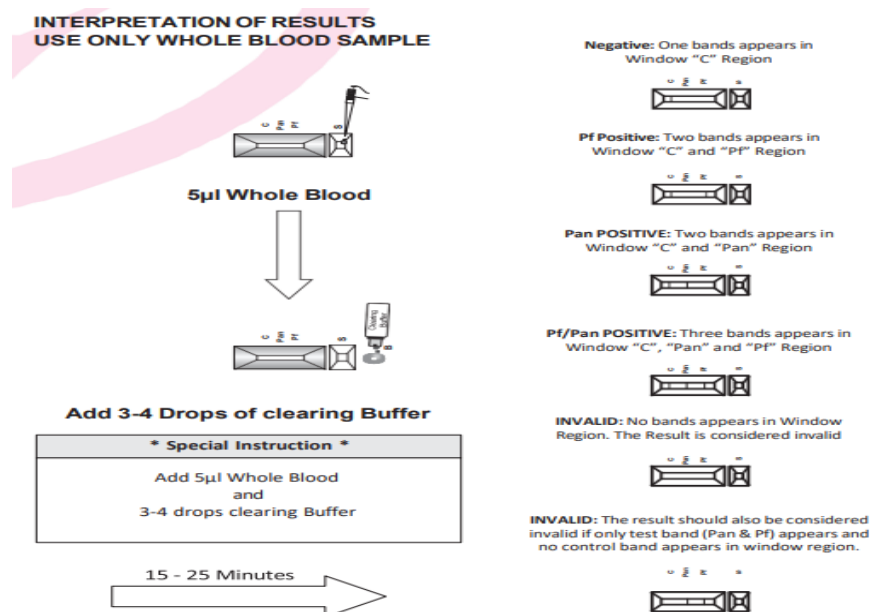
Maxline is a single device with no additional components or accessories. Maxline has been registered as a kit which consists of an Individually packed test device, buffer, sample dropper and package insert

Maxline is a manually operated device. It is used for diagnosis of Malaria. Maxline operates based on immunochromatographic assay, as the whole blood flows through the Nitrocellulose membrane assembly after addition of clearing buffer, the anti P.f 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 is immobilized by the Anti Pf. HRP-2 and anti-Pan specific antibodies coated on the nitrocellulose membrane leading to the formation of Colored bands which confirms a positive. If both the bands P.f or P.f & Pan appear together, the blood sample is infected with falciparum. If only one Pan Band is appeared in non-falciparum malaria positive samples. Absence of both colored lines indicates a negative test. Appearance of Colored band at the control line C serves to validate the test performance. The test out-put is qualitative.

The type of specimen used is human whole blood samples and is collected by venous blood collection and fingerpicks

Description

The HCV One Step Test Device (Serum/Plasma/Whole Blood) is a qualitative, membrane-based immunoassay for the detection of antibody to HCV in Serum/Plasma/Whole Blood



2.3. Commercial presentation

There are 10,20,25,30 and 50 approved commercial presentations as follows: One individually packed test device in the primary pack in foil pouch. 10,20,25,30, 50 depend on the box size are placed in secondary box.

Additional contents include Each kit contains:

- a) Buffer
- b) Sample Dropper
- c) Product insert

2.4. Items required but not submitted

- a) Specimen collection containers
- b) Stopwatch
- c) Syringe

3. Storage instructions

3.1.1. Shelf-life

The approved shelf-life is 24 months.

3.1.2. Storage conditions

The recommended storage conditions are (4-30°C).

3.1.3. Shipping conditions

The recommended shipping conditions is 4-30°C

4. Manufacturing site audit

The manufacturer of the device is Avecon Healthcare Pvt. Ltd, Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India – 133104.

Quality audit of the manufacturing facility was conducted through site visit on 10th - 11th October 2024. The site was found to be compliant to ISO 13485 requirements.

5. Performance Evaluation

5.1. Analytical Performance

The analytical performance characteristics of the device was established through the following test parameters: precision (repeatability and reproducibility), analytical sensitivity and analytical specificity.

5.2. Clinical Performance

Clinical performance was conducted at KCRI (Kilimanjaro Clinical Research Institute) Biotechnology Laboratory. The following parameters were tested clinical sensitivity and clinical specificity

Based on results of the performance studies, it was concluded that the test sensitivity and specificity is 100% and 100% respectively. The studies further concluded that Maxline is capable of consistently producing accurate and reliable test output.

6. Product label and instructions for use

The content of the primary and secondary labels is in line with TMDA labeling requirements in terms of content, layout and design. The label contains sufficient information for proper identification of the device and post marketing follow up of the product in the market.

The package inserts and instructions for use includes all the relevant information to ensure correct and safe use of the device by intended user.

6.1. Primary pack



6.2. Secondary pack



6.3 Instructions for use/Package insert

For assessing package insert click here below but also you can read it on last page



Q5 IFU - Malaria Ag
Pf-Pan Rapid Test.pdf

7. Risk – Benefit Analysis

On basis of the data submitted, the current state of knowledge and compliance of the manufacturer to ISO 13485, the benefit of the product outweighs the risks associated with its use when used in accordance to the manufacturer instruction. Maxline is recommended for registration.

8. Post-approval updates

8.1. Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date
NA	NA	NA	NA	NA

8.2. Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response
No any recorded Adverse Event	NA	NA

8.3. Re-registration applications

NA

CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

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 clearing 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 is immobilized by the Anti Pf, HRP-2 and anti-Pan specific antibodies coated on the nitrocellulose membrane leading to the formation of Colored bands which confirms a positive.

If both the bands Pf or 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 colored lines indicates a negative test. Appearance of Colored 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 uses beyond the expiration date. Once opened, the test device gives accurate result till 60 minutes but it is recommended to used immediately.

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 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

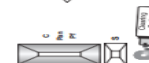
1. Clean the fingertip with the alcohol swab, and let dry completely. Prick the fingertip with a single use lancet.
2. Collect 5 µl of blood using the sample dropper up to the mark or pipette.
3. Load the 5 µl of blood into the sample well "S" of the test device.
4. Add 3-4 drops (100 ul) of assay buffer 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 3-4 Drops of clearing Buffer

*** Special Instruction ***

Add 5µl Whole Blood and 3-4 drops clearing 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/ul of blood for Pf and 200 parasites/ul 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

1. Baker J., et al, Olos one, 6(7), 2011, 1-10.
2. Clinton, K. et al, Intersicriplinary Prespective on Infections Diseases, 1155, 2009, 1-7.
3. Howard R. J. et al, J. Cell Biol, 103, 1986, 1269-1277.
4. Moody, A., Clinical Microbiological Review, 15(1), 2002, 66-78.
5. Malcolm, J.G. et al, 2002, Nture 419, 2002, 498-511
6. Perlmann, P. and Troye-Blomberg, M. 2002... Malaria parasites and disease. Malaria Immunology.
7. Pipe, R. G., et al, 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 Orgnaization-Geneva, New Perspective malaria diagnosis 2000.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	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



AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576

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 clearing 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 Colored bands which confirms a positive.

If both the bands Pf or 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 colored lines indicates a negative test. Appearance of Colored 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 uses beyond the expiration date. Once opened, the test device gives accurate result till 60 minutes but it is recommended to used immediately.

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 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

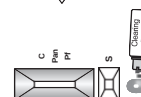
1. Clean the fingertip with the alcohol swab, and let dry completely. Prick the fingertip with a single use lancet.
2. Collect 5 µl of blood using the sample dropper up to the mark or pipette.
3. Load the 5 µl of blood into the sample well "S" of the test device.
4. Add 3-4 drops (100 ul) of assay buffer 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

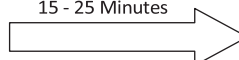


Add 3-4 Drops of clearing Buffer

* Special Instruction *

Add 5µl Whole Blood
and
3-4 drops clearing 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/ul of blood for Pf and 200 parasites/ul 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

1. Baker J., et al, Olos one, 6(7), 2011, 1-10.
2. Clinton, K. et al, Intersicriplinary Presperspective on Infections Diseases, 1155, 2009, 1-7.
3. Howard R. J. et al, J.Cell Biol, 103, 1986, 1269-1277.
4. Moody, A., Clinical Microbiological Review, 15(1), 2002, 66-78.
5. Malcolm, J.G. et al, 2002, Nture 419, 2002, 498-511
6. Perlmann, P. and Troye-Blomberg, M. 2002.. Malaria parasites and disease. Malaria Immunology.
7. Pipe, R. G., et al, 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 Orgnaization-Geneva, New Perspective malaria diagnosis 2000.

Symbols Used on Pack

	Catalogue Number		Warning/Caution
	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



AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations

Plot No.: 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.

E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com

Customer Care No. : +91 93065 12576